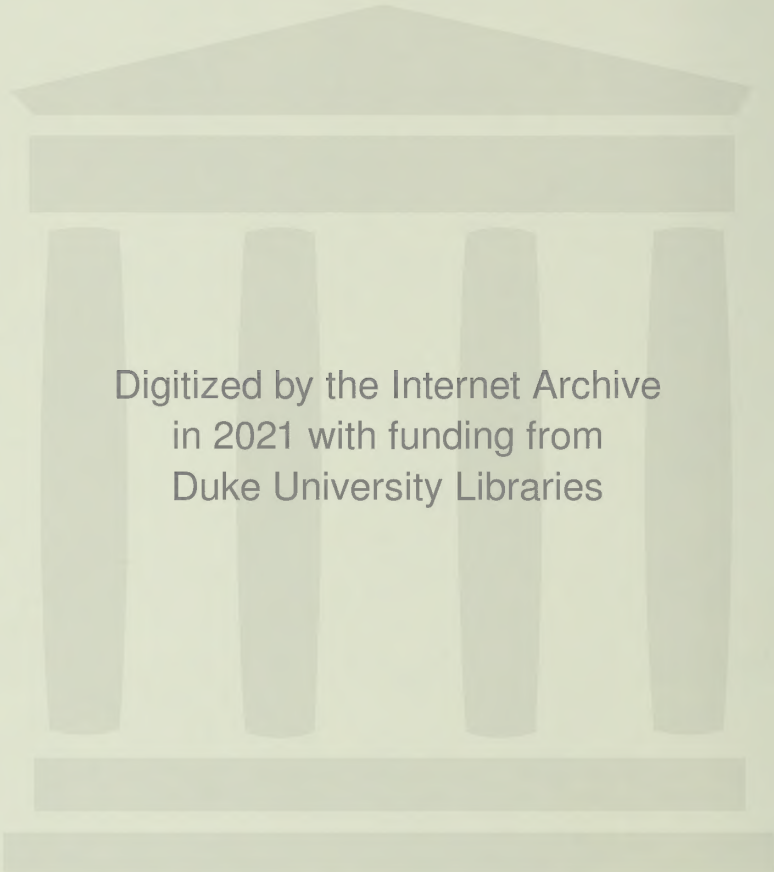
Organ Transplantation Policy



Organ Transplantation Policy

Issues and Prospects

Edited by James F. Blumstein and Frank A. Sloan

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Introduction

James F. Blumstein and Frank A. Sloan,
Vanderbilt University

The orientation of health policy during the last decade has shifted toward a greater reliance on market mechanisms. This shift has resulted in an increased focus on multiple options for consumers and disclosure requirements. The evolution of the legal doctrine of informed consent has given patients in many states a more active role in decisionmaking. There has been recognition, even in recently enacted regulatory programs such as the Medicare prospective payment system, of the importance of incentives. Health policy has been characterized by growing respect for diversity, pluralism, and decentralization. The general rethinking of the balance between regulation and competition has suggested that the role of government should be to enhance the operation of markets rather than substitute for them.

A notable exception to the trend toward the competitive, market-driven approach to health care is the field of organ transplantation. The thrust of federal organ transplantation policy is highly regulatory, as spelled out in the National Organ Transplantation Act of 1984 and the 1986 Budget Reconciliation Act; in the U.S. Department of Health and Human Services (DHHS) regulations concerning Medicare and Medicaid reimbursement for organ procurement and transplantation services in 1987 and 1988; in the policies of the federally mandated and designated organ procurement and transplantation network, the United Network for Organ Sharing (UNOS); and in the recommendations of the congressionally mandated Task Force on Organ Transplantation, upon which federal policy has largely been based. As the articles in this volume point out, regulation permeates all aspects of organ transplantation activity. Organ procurement takes place in a framework of "required request," prohibition of financial remuneration for organ donations, and monopoly of procurement activities by organ procurement organizations in discrete catchment areas. Allocation of organs is regulated by a national, computerized system of organ sharing based on numerical points. Provision of transplantation services is restricted by DHHS and UNOS regulation to centers that meet certain criteria.

The striking contrast in emphasis between the mainstream of health policy in the last ten years and organ transplantation raises an overarching question: Does the difference in policy prescription in the organ transplantation arena reflect a kind of sub rosa, underground rejection of the trend toward greater competition,

pluralism, and decentralization in the health care industry, or are there certain peculiar characteristics of the organ transplantation enterprise that suggest the inapplicability of competition, pluralism, and decentralization in this specific industry? This question formed the basis for the national invitational symposium on "Organ Transplantation Policy: Issues and Prospects" that we organized, with funding provided through a grant from the HCA Foundation. At this symposium, held on 26–28 June 1988 at the Health Policy Center of Vanderbilt University's Institute for Public Policy Studies, the first seven papers in this collection were presented. The symposium authors and participants were an interdisciplinary group of about 50 organ procurement and transplantation practitioners, federal and state officials and policymakers, and scholars in law, ethics, economics, and policy analysis. They represented a broad range of perspectives on the social, ethical, and policy issues concerning organ transplantation discussed in these papers. While each paper focused on a particular aspect of organ transplantation policy, inevitably and intentionally the papers cut across topical areas, so the symposium reflected a variety of views on each issue.

In the overview chapter, James Blumstein demonstrates the fundamental importance of ideology in the evolution of federal transplantation policy and questions some of the premises underlying development of that policy. His analysis leads to a call for a reassessment of the relationship of the privately run organ procurement and transplantation network and the federal oversight agency (DHHS), and for greater authority for substantive policy setting to reside with the federal agency. Blumstein concludes that the existing federal legislation, which authorizes greater federal oversight, should be exercised to promote a more pluralistic, decentralized system. He notes that the 1986 requirement that all procurement agencies and transplant centers be members of the network in order to retain their Medicare and Medicaid eligibility fundamentally alters the nature of the network and makes the case for enhanced governmental oversight very strong.

Four authors in this volume present a range of views on policy concerning the procurement of organs, whose scarcity is a unique feature of the organ transplantation industry. Jeffrey Prottas emphasizes the improvement in the effectiveness of organ procurement activities in recent years and suggests that tinkering at the margins of the current system is the best approach to increasing organ supply. He concludes that donations will increase as organ procurement organizations concentrate their "marketing" focus on hospital personnel in intensive care units, who are typically reluctant to make the requests, rather than on families, who are usually willing to donate if asked. Richard Rettig suggests, in contrast, that current regulatory efforts to reorganize the procurement system in order to increase the organ supply may be creating an overorganized and bureaucratized system, with the unintended consequence of impairing the system's actual performance. Henry Hansmann challenges the conventional view, embodied in federal policy, that bars financial remuneration for donated organs. He proposes that markets might well serve a useful role in increasing the overall supply of organs, and proposes the

legalization and development of markets for organs as an alternative to the current nonmarket approach. On the other hand, James Childress supports current donation policy, based on an ethical analysis that takes into account fundamental moral principles including respect for persons, beneficence, nonmaleficence, and justice. His evaluation of various approaches to the acquisition of organs, including donation, sales, abandonment, and expropriation, concludes that the policy of required request is the preferable approach at this time.

Regarding the dispositional authority over donated organs, James Blumstein and James Childress offer contrasting views. Blumstein raises philosophical, legal and pragmatic questions concerning the national system for organ sharing, while Childress argues for the communitarian approach to organ sharing that is embodied in current national policy.

Whether and under what circumstances government has a responsibility to pay is a central issue in organ transplantation. Peter Schuck examines federal and state payment patterns and the principles that underlie them. He finds that, on balance, the arguments in favor of special entitlement programs that finance organ transplantation services are unsatisfactory. His analysis leads to the prediction that, as organ transplantation becomes a more common occurrence and loses its "privileged political status," it will compete on more equal terms with other social goods for scarce government resources, a positive direction that he believes government should encourage. Rettig's account of the evolution of federal government policy, which touches on the related issues of financing, distributive justice, and rationing, concludes that financing of organ transplantation faces severe fiscal constraints that will force painful policy choices.

Organ transplantation policy has been characterized by a strong push for regionalization by federal and state government and private payers. The stated goals of ensuring quality, containing costs, and encouraging research by concentrating transplant procedures in certain centers may be accompanied by unspoken aims of limiting market entry in order to protect the position of existing centers. Frank Sloan, May Shayne, and Marilyn Doyle review the empirical evidence for regionalization policy in organ transplantation, point out the pitfalls of using volume as a proxy for quality in designating transplant centers, and suggest alternative approaches. Using a national database from Medicare's end-stage renal disease (ESRD) program, they perform an analysis of the relationship of survival of kidney grafts, ESRD patient posttransplantation survival, and charges to the number of transplants performed per hospital and surgeon. The results suggest that, at least for kidney transplants, there is no systematic association between volume and outcomes. However, charges tend to be lower at the larger centers. Richard Rettig suggests that temporarily limiting procedures to designated centers until surgeries are proven efficacious may be sensible, but shares the caution of Sloan, Shayne, and Doyle about policies that tend to establish permanent franchises based upon poor empirical evidence.

The final chapter in this volume presents an earlier paper that played an impor-

tant role in focusing attention on many of the difficult issues involved in setting organ transplantation policy. Although Havighurst and King's paper appeared in 1986, as part of an *Indiana Law Review* symposium on "Hard Choices and Ethical Dilemmas" in health care, we believe its presence in this volume serves to bring into clearer focus through a case example many of the issues that are treated in a more theoretical manner elsewhere in the book.

Taken as a group, the papers serve to emphasize the dilemmas society will face as new technologies, many of which are very costly, become available for widespread use. Society must not only decide what and how to pay for specific services, but also who should bear the burden and how delivery of care should be organized. Solid organ transplantation is unique in one major respect, however. Human organs are scarce, and as the technology improves, demand will inevitably increase. The dilemma is how to balance the rights of the patient in need of a transplant, for whom transplantation is often a matter of life or death, against the rights of the donor, the donor's family, and the society at large.

Government's Role in Organ Transplantation Policy

James F. Blumstein, Vanderbilt University

Abstract. This paper initially considers ways of thinking about organ transplantation: Should it be treated as a catastrophic disease or as an ordinary and accepted medical procedure? The analysis then shifts to the role the government has played in influencing organ transplantation policy. The federal government's involvement initially stemmed from its role as payer for end-stage renal disease services. In recent years, the rationale for intervention has changed, and the mechanism for implementing regulatory oversight has shifted to a private network run for the government by the United Network for Organ Sharing (UNOS). The government has delegated much policymaking authority to UNOS, although the author demonstrates that this is not required by the applicable legislation. The article raises questions about the relationship between UNOS and the federal government, about potential conflicts between UNOS guidelines and state laws under the Uniform Anatomical Gift Act, and about the ideological stance undergirding much of current federal policy in the organ transplantation arena.

Introduction

It is difficult to develop a neutral framework for analyzing organ transplantation policy. No matter how one shapes the issues, a bias seems to drive the analysis. Indeed, the policy analyst being initiated into the complex world of organ transplantation policy comes away from an initial immersion struck by the overwhelming overlay of ideology—sometimes express, but often implicit—that permeates the field. Given the high stakes involved—for payers, for providers, and most especially for patients—it is perhaps unsurprising that ideology seems to have played and continues to play such a fundamental role in the evolution of public policy. Despite the dramatic progress that has characterized the field of organ transplantation, it seems universally agreed that significant problems continue to beset the organ transplantation enterprise, particularly (although not exclusively) in the area of transplantable organ supply (U.S. DHHS 1986). Ideological dogma may have

contributed to these problems by excessively and prematurely influencing public policy.

In what follows, I will first consider the broader health policy context within which organ transplantation policy issues must be analyzed. I will show how different theoretical perspectives influence the debate about governmental financing for organ transplantation. I will then examine the development of federal organ transplantation policy and place it within the broader context of health policy evolution. The analysis will show that government's role as payer in the kidney area has explained much of government's initial regulatory thrust but that government's regulatory role—and its rationale for intervention—have changed considerably in the past several years.

The development of organ transplantation policy has been driven by a philosophical or ideological perspective that is fundamentally different from the perspective that has driven other facets of health policy in the last decade. This development has been influenced by the 1986 report of the national Task Force on Organ Transplantation and facilitated by a privately operated transplantation network that, with acquiescence and tacit approval from the U.S. Department of Health and Human Services (DHHS), has embraced the ideology of the task force. It is interesting to speculate whether this difference reflects a principled departure from the procompetitive approach that has been ascendant recently in other facets of the health policy arena (Blumstein and Sloan 1981; Greenberg 1988), or whether it reflects a confrontation with and rejection of the modish, procompetitive ideological mainstream.

In any event, as I discuss briefly in the concluding section, there may be constraints external to organ transplantation policy that act to delimit the noncompetitive or even anticompetitive aspects of organ transplantation policy as developed independently by the transplantation network. To the extent that the autonomy of the transplantation network is observed (so that its decisions reflect private concerted action of a potentially anticompetitive character as enforced by federal mandate), the policies of the network are likely to become subject to serious antitrust scrutiny and potential challenge. The antitrust laws, therefore, may well be invoked to contest the propriety of the threat that evolving organ transplantation policy poses to the competitive norms embraced by those antitrust laws.

The policy context

Organ transplantation as a catastrophic disease. At the most basic level, organ transplantation policy is a subset of a broader, generic health policy issue—the problem of coping with the costs of catastrophic disease. For years, there has been a debate in health policy circles about the best way to conceptualize the very special problems posed by catastrophic disease.[1] Should the nature and effect of

1. For an interesting statement on this issue, see the speech of Senator Quayle (Congressional

the illness—e.g., whether it is life-threatening—guide our thinking? Or should the financial consequences of an illness—whether it be an acute, life-threatening episode or a long-term, chronic problem—be determinative (Havighurst, Blumstein and Bovbjerg 1976)?

Although far from comprehensive (because of its exclusive focus on the costs of acute care for the Medicare population), the recently enacted Medicare Catastrophic Coverage Act of 1988 reflects adherence to the financial definition. The act addresses a portion of the broader problem of financial disruption or potential bankruptcy that can stem from extremely expensive episodes of acute illness. The drug benefit, although not limited to the organ transplantation context, clearly will have an impact in the organ transplantation arena. By providing reimbursement for prescription drugs after a substantial deductible, the new legislation will ease the financial impact on patients of the high cost of postoperative immunosuppressive drugs such as cyclosporine. These antirejection drugs are an essential component of the organ transplantation course of treatment and an important ingredient in recent improved success rates. Under current Medicare legislation, government will pay for immunosuppressive drugs for eligible transplant patients for only one year after the date of the transplant procedure.[2] The financial consequences of subsequent out-of-pocket expenses for immunosuppressive drugs can be substantial—i.e., "catastrophic."

Although many analysts have favored the financially oriented conception of catastrophic illness, until the enactment of the recent catastrophic disease amendments to Medicare the disease-specific approach was the path pursued in the federal public policy arena. Examples include legislation directed toward improving care for heart disease, cancer, and strokes[3] and legislation designed to assist miners suffering from black lung disease (pneumoconiosis).[4] Of course, the inclusion in 1972 of most victims of end-stage renal disease (ESRD) within Medicare is a dramatic and most germane illustration of this disease-by-disease approach.[5] The 1972 ESRD legislation included Medicare coverage for kidney dialysis and kidney transplantation. As evidence of improved efficacy and cost effectiveness became available, transplantation became the preferred mode of treatment of ESRD under the ESRD Medicare program (Eggers 1988). Thus, in the current policy context, organ transplantation policy must be understood within the framework of the broader

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Record, 17 June 1988, pp. 58095–96) concerning a proposed block grant program for immunosuppressive drugs. Quayle objected to the creation of a disease-specific program because he could not justify "singling out immunosuppressive drugs when there are other expensive drugs needed by many individuals with life-threatening illness" (p. 58096).

2. Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9335(c), 100 Stat. 2009 (1986).

3. Heart Disease, Cancer and Stroke Amendments of 1965, Pub. L. No. 89-239, 79 Stat. 926 (1965) (codified at 42 U.S.C. § 299).

4. Federal Coal Mine Health & Safety Act of 1969, Pub. L. No. 91-173, 83 Stat. 792 (1969), and Black Lung Benefits Act of 1972, Pub. L. No. 92-303, 86 Stat. 153 (1972).

5. Pub. L. No. 92-603, §2991 (1972).

health policy debate concerning the proper approach to catastrophic disease and the nature and scope of government's appropriate role in dealing with that most ticklish health policy issue.

As a form of treatment for ESRD, kidney dialysis satisfied both definitions of a catastrophic disease. Without dialysis (or transplantation), ESRD is surely life-threatening. With dialysis, ESRD patients could look forward to a decent prognosis for sustenance and an acceptable quality of life. However, in the absence of a source of subsidy, not all those who could benefit from its use would be able to take advantage of that lifesaving treatment. Advocates for including dialysis within the scope of Medicare were able to exploit society's unwillingness to engage in nice calculations of costs and benefits when a clearly identifiable life was in the balance. The skillful use of "symbolic blackmail" (Blumstein 1981) helped to explain the initial legislation that included coverage for ESRD patients in the Medicare program (Rettig 1976).

Not all such potentially worthy illnesses have found shelter under the federal financial umbrella, however, and the current debate about the nature and scope of governmental responsibility with respect to transplantation of extrarenal organs must be understood within this broader health policy framework. Should federal financial support for organ transplantation be extended beyond the realm of the kidney program to cover hearts, livers, and other extrarenal organs? The case for federal financial coverage for transplantation of extrarenal organs can be argued either within the context of a generic financially based catastrophic disease program or using a disease-by-disease approach.

The financial approach is straightforward. Once expenses surpass the threshold defined as catastrophic—whether expressed in absolute dollars or as a percentage of income—the organ transplantation episode would qualify for catastrophic coverage. The nature of the illness would be irrelevant. Only the cost would matter. Any special characteristics of organ transplantation would become beside the point.

For extrarenal organ transplantation to secure preferred status under the disease-by-disease approach, advocates must pursue the following simultaneous arguments: that transplantation of extrarenal organs has the same virtuous characteristics associated with transplantation of (or dialysis of) kidneys; that the extension of federal financial support to dialysis and transplantation of kidneys has, on balance, been an effective program worthy of expansion and emulation in the area of extrarenal organs; and, finally, that transplantation of extrarenal organs constitutes a higher social priority (including symbolic values) than other catastrophic diseases also competing to enter the coveted inner circle of federal financial support.[6]

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6. Although at first blush the foregoing framework for analyzing organ transplantation policy seems straightforward enough, it proceeds under a fundamental (albeit unarticulated) ideological assump-

Consideration of organ transplantation policy within the framework of catastrophic disease policy implicitly assumes that the catastrophic label has policy implications—that is, that the nature and scope of government's role with respect to catastrophic diseases may well differ from its role or obligations in other areas of health policy. Thus, advocates for further governmental financial support for the transplantation of extrarenal organs can seek to make the case that government has a special responsibility to deal with catastrophic disease. They would distinguish transplantation from other, more "normal" types of treatment. The extraordinary lifesaving characteristics of transplantation would be the basis for including diseases for which transplantation is necessary within the "catastrophic" category. Those characteristics, when combined with evidence of clinical efficacy, would undergird the argument for assigning extrarenal organ transplantation a high priority within that inner circle of treatments for "catastrophic" illnesses.[7]

Organ transplantation as part of "adequate" or "ordinary" care. If, following the recommendations of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1983), the analyst assumes that government has an obligation to provide an adequate level of medical care to citizens without imposing an undue financial burden on them, the nature of the case for covering extrarenal organ transplantation becomes quite different. In that situation, the special or extraordinary character of catastrophic disease diminishes in importance, and the fundamental nature of extrarenal organ transplantation as an accepted and effective course of treatment for life-threatening illness becomes the centerpiece of the argument. In this scenario the case for covering extrarenal organ transplants is not based on their extraordinary character,

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tion—namely, that organ transplantation is potentially deserving of special attention because of its claim to status as a treatment for a catastrophic disease (however defined). It suggests that society has a special responsibility to provide for coverage of catastrophic diseases. It also suggests that public responsibility for paying for medical care might properly be limited. While it is clear that organ transplantation issues do properly fall within the broader category of catastrophic illness, it is not so apparent that the very recognition of a distinct category of illness as "catastrophic" tends to blur a critical ideological assumption. That is, "viewing catastrophic illness as an independent policy problem calling for independent financing appears to presuppose that government's obligation to assure the provision of medical services is not unlimited. For this reason, proponents of a national cradle-to-grave health care system . . . would not regard particular illnesses or particular levels of expenditure as a separate problem. In their view, equity requires a redistributive allocation of in-kind medical benefits across the board to assure equal access to all types of health care, whatever the health problem. Focusing on catastrophic care may be seen as betraying a fundamental tenet, unacceptably providing only half a loaf" (Havighurst, Blumstein and Bovbjerg 1976: 129–30).

7. To be sure, there is a certain awkwardness about focusing on the mode of treatment—transplantation—rather than focusing on the underlying illness itself in claiming status within the catastrophic disease category. Yet in the current state of affairs, extrarenal organ transplantation is typically viewed as a last-resort regimen for coping with what would otherwise be a life-threatening illness. Understood that way, organ transplantation is a proxy both for catastrophic (i.e., life-threatening) disease and for a financially extensive and expensive course of treatment. Classification of organ transplantation in which life-threatening indications are not present would pose other issues.

but on the argument that organ transplantation is now part of the customary and accepted practice of medicine and should be encompassed within government's obligation to provide access to an "adequate" level of medical care for those unable to pay for it without incurring an undue burden (Blumstein 1988a).

Within the framework of existing entitlement programs (such as Medicare), the case for coverage is that extrarenal organ transplantation is a reasonable and necessary mode of treatment, and inclusion of this treatment modality is mandated for covered beneficiaries under existing law (which requires coverage for reasonable and necessary medical care). This argument from "normalcy" was precisely the basis upon which the federal government was persuaded to include heart transplantation within the scope of Medicare coverage. After reviewing the findings of the Battelle National Heart Transplant Study, DHHS "determined that, for Medicare coverage purposes, heart transplants are medically reasonable and necessary when performed in facilities that meet certain criteria."[8]

Policy implications of choosing an analytical framework. The way we think about federal funding for extrarenal organ transplantation turns in part on broader questions concerning the scope of governmental responsibility for providing access to medical care. The selection of analytical frameworks involves more than an abstract intellectual nicety; there are potentially significant policy consequences. For example, if organ transplantation is deemed part of society's obligation to provide an adequate level of care to impecunious individuals, resource scarcity might well raise the problem of expenditure priorities. (In this context, the Oregon debate concerning Medicaid coverage for organ transplantation is instructive—see Welch and Larson 1988). Should scarce public dollars be expended to provide basic medical care coverage to a group of otherwise uncovered medically needy persons, or should those funds be allocated to enhance coverage to the "adequate" level for persons already included within the state's basic medical public assistance program? Such an analysis does not consider the special role government may have with respect to catastrophic—in this case, life-threatening—illness.

If, however, government has a special duty to help citizens cope with the consequences of catastrophic, life-threatening disease, then it is inappropriate to engage exclusively in a medically oriented value comparison between expanding the number of medical public assistance beneficiaries and covering extrarenal organ transplants for a group of already-covered beneficiaries. Like the argument that won Medicare coverage of kidney dialysis in 1972 (Rettig 1976), the case for government coverage of catastrophic illnesses plays to the highly symbolic character of life-threatening disease. It recognizes that more is at stake than a purely medical calculation of how best to save lives or improve overall health status. Because they confront government with basic questions of society's humanitarian self-im-

8. 51 Fed. Reg. 37,164 (1986); 52 Fed. Reg. 10,935 (1987).

age, individual episodes of illness are likely to elicit public sympathy and to secure public support.

This insight would support an argument that the nature of the illness—i.e., its "catastrophic" status—should trigger a special governmental duty, if only for government to protect itself against its own ultimate unwillingness to make tough decisions in the highly symbolic life-and-death situation. By building such expenses into a rational, planned tax and expenditure structure, the government could avoid "free rider" problems (Havighurst, Blumstein and Bovbjerg 1976). Transplant proponents would assert that government's failure to pay for transplants would not save money in the intermediate and long run, because the lifesaving imperative (Havighurst and Blumstein 1975) would result in substantial public support for (and possibly eventual coverage for) the life-threatening illness. No such political push would exist for the less visible claims of uncovered potential beneficiaries of routine medical care that enhanced the quality of life.

With the policy debate structured in this manner, the nature of government's role and responsibility in the area of catastrophic disease would weigh in the balance. Policymakers would take into account the values associated with government support of identified citizens in dire straits. Public policy would be driven by a pragmatic recognition that any governmental refusal to pay for catastrophic illness such as organ transplantation would, in the longer run, be politically unstable because of the inevitable effects of symbolic blackmail. In the arena of public policy debate, this analysis would reduce the reliance on an exclusively medically oriented utilitarian balancing of organ transplantation against other medical services that government may be obligated to provide in principle.

The federal government's evolving role in organ transplantation

The ESRD program. By far the largest program of organ transplantation involves kidneys (U.S. DHHS 1986). This is no accident, since nearly all kidney transplants are covered by Medicare and therefore are paid for by the federal government. Federal payment for renal transplantation emerged from the federal commitment to pay for treatment for ESRD patients. Kidney transplantation has become an alternative and often more efficacious mode of treatment than dialysis for ESRD (Rettig 1976; Eggers 1988).

As a major payer for ESRD treatment, the federal government had a distinct role to play in assuring appropriate quality standards when public beneficiaries were undergoing treatment for ESRD. Although early programmatic bias for maintaining higher-cost treatment methods apparently reflected more the influence of providers than the interest of ESRD patients or federal taxpayers, it is undeniable that government has a special role in monitoring the cost and quality of services it purchases for designated federal beneficiaries. Particularly when it was operating in a health care environment notoriously lacking in incentives for efficiency, gov-

ernment quite legitimately took an interest in the structure of the kidney dialysis, procurement, and transplant systems. With the evolution of other, extrarenal organ transplantation technology, spurred in part by improved immunosuppressive drugs and more sophisticated tissue-matching capabilities, it was natural for policy analysts to use the kidney transplantation experience as a point of reference.

A tradition of sharing organs arose in the kidney arena. Because of the medical desirability of transplanting organs from donors who had certain physiological characteristics in common with recipients, it seemed only reasonable to develop a network for the more efficient use of scarce organs that became available through donation. Similarly, it was understandable for government to be concerned about standards of quality of entities eligible to receive federal compensation for renal transplants (Rettig 1989). As a prudent purchaser in an industry virtually entirely dominated by federal financing, the federal government legitimately became involved with establishing guidelines of eligibility for provider participation in the renal transplant program.[9] This tracked government's overall approach to providers seeking to participate in the Medicare program.

The National Organ Transplantation Act of 1984. In 1984, the National Organ Transplantation Act[10] began the process of developing a comprehensive framework for considering organ transplantation policy. The statute called for the formation of a task force to deal with specifically enumerated policy issues, and addressed issues of organ procurement and distribution by providing funds for grants to qualified organ procurement organizations and for the establishment of the Organ Procurement and Transplantation Network.

As clearly stated in the legislative history, Congress was responding to "major advances" in organ transplantation techniques.[11] Those technological advances had resulted in an 80 percent one-year survival rate for kidney transplant patients. In addition, the introduction of the antirejection drug cyclosporine had doubled the one-year survival rate for liver transplant patients from 35 to 70 percent. Congress thus viewed organ transplantation as providing "new hope" to thousands of patients whose end-stage organ failure would lead "inevitably to total disability and death."[12]

The Senate report noted that the number of patients on waiting lists for organ transplantation far exceeded the available supply of transplantable organs, a recurring and ongoing problem. According to available estimates, a relatively small percentage (about 15 percent) of potentially transplantable organs had been harvested. The Senate cited an estimate that "20,000 people die annually under cir-

9. See 42 CFR § 405.2100 et seq. (1987).
10. Pub. L. No. 98-507 (1984).
11. 1984 U.S. Code Cong. & Admin. News 3976.
12. *Id.*

cumstances that would make them suitable organ donors."[13] The subsequent report of the Task Force on Organ Transplantation (U.S. DHHS 1986) found that the reliability of estimates about potential organ donors was subject to question because of the wide range of estimates found in different studies. While acknowledging "the crude nature of present estimates," the task force concluded that "the potential donor pool for cadaveric organs probably lies between 17,000 and 26,000 donors per year" (ibid.: 35). For kidney transplantation purposes, the overall supply is enhanced by the 25–30 percent of total transplanted kidneys provided by living kidney donors each year (1,704 for 1984) (ibid.: 36).

The Senate report stated that a "limiting factor," particularly for liver and heart transplants, was "the small number of medical centers . . . equipped to carry out organ transplants."[14] Organ transplantation requires highly trained personnel and an extensive commitment of hospital resources.[15] The high cost of organ transplantation was also viewed as a "major hurdle" for many patients in need of a transplant.[16] The Senate report acknowledged that the nationwide publicity attendant to specific organ appeals had placed the organ transplantation issue squarely on the public agenda.[17]

The Senate report also recited the nongovernmental efforts that had developed in the areas of organ procurement and distribution, concluding that improvements were needed in the areas of organ donation, procurement, and distribution.[18] Thus, the objective of the 1984 legislation was to support development of "a rational and fair national health policy regarding organ transplantation."[19]

With one exception, the National Organ Transplantation Act of 1984 was not formally regulatory in character. Congress believed that, to the extent that a coordinating function needed to be performed, responsibility for it should be "located in the private sector rather than in government."[20] The act provided for the funding of the Organ Procurement and Transplantation Network (OPTN)[21] as a vehicle for improving the effectiveness of the organ transplantation enterprise. The role of the OPTN was to establish a registry of patients in need of organs for transplant and to develop a national system for matching donated organs and potential recipients listed on the registry. The OPTN was to assist organ procurement agencies distribute organs that could not be used in local service areas and to adopt and use uniform standards of quality for the acquisition and transportation of donated organs. The OPTN was also intended to have an educational mission, providing

13. *Id.*
14. *Id.*
15. *Id.* at 3977.
16. *Id.*
17. *Id.* at 3977 and 3979.
18. *Id.* at 3978.
19. *Id.*
20. *Id.* at 3981.
21. 42 U.S.C. § 274.

information to physicians regarding organ donation and collecting, analyzing, and publishing data concerning organ donation and transplantation.[22] The preexisting United Network for Organ Sharing (UNOS), a central computer registry of potential kidney recipients, was subsequently designated by DHHS as the OPTN.

The 1984 act also provided for grants for the planning, establishment, initial operation, and expansion of "qualified organ procurement organizations."[23] To qualify for a grant under the act an organ procurement organization (OPO) was required to be a nonprofit entity qualified to receive Medicare reimbursement for kidney procurement and with established procedures to obtain payment for non-renal organs provided to transplant centers. The geographic service area for an OPO had to be large enough to include at least fifty potential organ donors each year, and each OPO had to have either a board of directors or an advisory board with a statutorily specified array of professional and public representatives. To be qualified for a grant, an OPO had to have agreements with a "substantial majority" of institutions in its service area that had facilities for organ donation. The applicant OPO was also required to participate in the OPTN, adopt standards of organ acquisition, preservation, and quality consistent with those of the OPTN, arrange for tissue typing of donated organs, have a system for allocating donated organs among transplant centers and patients "according to established medical criteria," and arrange for the transportation of donated organs to transplant centers.[24]

Participation in the OPTN and the establishment of relationships by transplant centers with the procurement agencies to be funded were not obligatory. To the extent that the OPTN was useful and provided a service, transplant centers and their patients were able to benefit from the system of coordination. To the extent that other avenues of donation and procurement were available and more attractive, transplant centers and their patients were free to utilize those other sources and resources as well.

Interestingly, the one explicitly mandatory regulatory provision of the 1984 act was its ban on the purchase or sale of human organs, as that would affect interstate commerce.[25] Under the statute, the term "human organ" was defined extremely broadly to cover "the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin, and any other human organ specified by the Secretary of Health and Human Services by regulation." Remarkably, the legislative history on this provision is extraordinarily sparse. The Senate report simply stated, "It is the sense of the Committee that individuals or organizations should not profit by the sale of human organs for transplantation," but distinguished the sale of blood and blood derivatives, since "blood and blood derivatives . . . can be replenished

22. 42 U.S.C. § 274(b)(2).
23. 42 U.S.C. § 237(a)(1)-(2).
24. 42 U.S.C. § 273(b)(2).
25. 42 U.S.C. § 274e(a).

and . . . donation does not compromise the health of the donor. . . . The Committee believes that human body parts should not be viewed as commodities."[26] The conference report is no more illuminating, merely indicating that the statute "intends to make the buying and selling of human organs unlawful."[27]

The ban on the purchase or sale of organs was thus one of the first federal regulatory measures concerning organ transplantation that was unrelated to the federal government's role as payer. By prohibiting the sale, receipt, or transfer of a human organ "for valuable consideration," the government restricted the development of any type of direct financial inducement for enhancing the supply of organs, despite the congressional finding that the supply of transplantable organs fell far short of the medical need (Andrews 1986). The Senate report's distinction of blood sales is of particular interest. The report's evident concern about compromising the health of the organ donor suggests its relevance to sales of organs by live donors; it would not seem to bear on the question of purchase or sale of cadaveric organs, even if the consideration were paid during a person's lifetime. The report does not explain, however, why the committee believed that "individuals or organizations should not profit by the sale of human organs for transplantation" but that profit from the sale of blood was acceptable.

The ban on the purchase or sale of organs for transplantation has shaped further development of transplantation policy and has constrained the options available for the evolution of transplantation policy (ibid.). Certain potential pathways—such as experimenting with markets for organs and with various forms of financial inducements for organ "donation"—must now remain unexplored (Hansmann 1989; Vining and Schwindt 1988; Schwindt and Vining 1986).[28]

The 1986 Budget Reconciliation Act. In May 1986, the Task Force on Organ Transplantation, which was convened under the terms of the National Organ Transplantation Act of 1984, transmitted its final report (U.S. DHHS 1986). The task force recognized the need to secure more transplantable organs; a shortage in supply of organs constrained further development of this promising mode of treatment. The task force lamented the relatively small percentage of potentially transplantable organs that were actually harvested for transplantation, and urged an array of public

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26. 1984 U.S. Code Cong. & Admin. News 3982.

27. *Id.* at 3992.

28. To the extent that organ life can be extended, opportunities for transfer increase. There is a technological question about the length of time organs can be preserved for transplantation. Recent evidence suggests advances in organ preservation (New York Times 1988). If the length of time between organ procurement and organ transplantation can safely be extended, there is a greater likelihood that organs can be transported and otherwise distributed more widely, with better chances for improved tissue matching (Opelz 1988; Salvatierra 1988). The ban on the purchase and sale of organs and a proposed alternative are discussed by Hansmann (1989). For present purposes, it is noteworthy that the technical factors that would allow some type of market in organs to develop are likely now in place. The issue, however, is intensely ideological—an example of the extraordinary importance of ideology in the evolution of organ transplantation policy.

education outreach activities to encourage more individuals and families of potential donors to think positively about donating organs.

The task force's approach to increased organ donation placed the value of increasing the supply of organs in the context of broader communitarian values. Quoting a Hastings Center Report, the task force stated that it was important to develop organ transplantation policies that promoted "the value of social practices that enhance and strengthen altruism and our sense of community" (ibid.: 28). Specifically, the task force considered the goal of "promoting a sense of community through acts of generosity" as a core value shaping organ transplantation policy, even if intensive educational and media campaigns would be needed to encourage this sort of altruistic act by families of dying patients (ibid.).

To effectuate this policy—which, strictly speaking, is unrelated to organ transplantation but uses the arena of organ transplantation to make a broader symbolic and political statement—the task force recommended that hospitals adopt policies requiring that families of dying patients be routinely asked to consider donating organs of their dead or dying next of kin. The ostensible rationale is that families, who have the legal authority to donate organs of their next of kin (National Conference 1968), should be given an opportunity to do a good deed for society and feel good about themselves by donating the organs of their dying relative to the commonweal. In the task force's view, once donated, the organs become a national resource, beyond the control of the donor or his family, so the decision to donate should be altruistically motivated. The task force felt that the routine inquiry policy should be institutionalized because individual professionals typically feel squeamish about raising these sensitive issues with family members in these delicate circumstances. An institutional rule would make the organ donation inquiry an obligation.

The 1986 Budget Reconciliation Act[29] implemented this facet of the task force's recommendations by adding Section 1138 to the Social Security Act. Using a hospital's eligibility to participate in Medicaid or Medicare as the coercive lever, Section 1138 requires all Medicaid or Medicare hospitals to institutionalize a required request policy. Such hospitals must establish written protocols for identifying potential organ donors and for notifying an organ procurement agency of the existence of a potential organ donor. These protocols must "assure that families of potential organ donors are made aware of the option of organ or tissue donation and their option to decline."[30]

Thus, the 1986 legislation used a hospital's Medicaid or Medicare participation as the mechanism for imposing on transplant hospitals a set of coercive, federal regulatory requirements concerning organ procurement. The clear goal of this portion of the 1986 legislation was to increase the percentage of actual organ donors

29. Pub. L. No. 99-509.
30. *Id.* at § 1138(a)(1)(A).

from the pool of potential donors. Although the statute was drawn carefully to protect the neutrality of the organ donation inquiry (families have to be informed of their option to donate and of their option to decline donation), the apparent assumption of the proponents was that, given positive societal attitudes toward organ donations, routine inquiries would yield affirmative family responses. Indeed, the implementing regulations published by DHHS establish as a condition of recertification for an OPO that it must meet specific performance standards concerning the number of transplantable kidneys it secures annually (23 cadaveric kidneys per million population of its service area).[31]

The statutorily mandated technique for achieving this goal—others are permitted—relies on securing approval from families of potential donors at the time of the patient's critical illness or at the time of death. In some circumstances, particularly when a dying family member is too young to be able to have considered the possibility of organ donation, the bedside opportunity to help others through organ donation may be psychologically fulfilling to a family—a demonstration that out of a loved one's death may come some compensating benefits after all. Despite the opportunity for this type of fulfillment, bedside confrontation with the issues of a dying family member's body parts is scarcely an optimal time from the perspective of a grieving family. The mandatory statutory focus on that time and place is of questionable taste or efficacy.[32]

Although the Uniform Anatomical Gift Act (UAGA) allows potential donors to control disposition of their organs by signing donor cards, apparently too few people sign those cards (U.S. DHHS 1986). The ban on financial inducements means that incentives are reduced for salespersons or others to seek out potential signees actively. Further, in the absence of a quid pro quo for the signing of a donor card and despite the legal authority derived from the UAGA to honor signed donor cards, the custom and practice in the organ transplant community is not to rely on a signed donor card but to seek independent approval from the family of a potential donor (Robertson 1987). That custom would surely change were the signing of the "donor" card viewed as contractual in character—paid for, thereby conferring rights on the contracting party. The entire nature and perception of this transaction would necessarily change, as would the status of the earlier decision of a potential "donor" to commit to the use of his cadaveric organs for transplantation. If nothing else, such a contractual arrangement would create at least one (and possibly several) interested parties that could be counted on to seek enforcement of their contractual rights aggressively.

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31. 53 Fed. Reg. 6526, 6551 (1988), to be codified as 42 C.F.R. § 405.306.

32. Families may suffer emotional distress when their next of kin is not cut off from life support systems promptly upon a determination of brain death. The request to a family for organ donation can create a painful, stressful dilemma, and can delay the return of a loved one's body as family members ponder the donation decision. For a case upholding a family's cause of action for emotional distress against a hospital in such a circumstance, see Strachan v. John F. Kennedy Memorial Hospital, 109 N.J. 523, 538 A.2d 346 (1988).

One clear cost of the absolutist stance embraced in the 1984 legislation—i.e., the flat-out ban on the purchase or sale of organs for transplantation—is the necessary emphasis on the request to families of potential organ donors at the time of a loved one's fatal illness. The unwillingness of transplant teams to accept organ donor cards, the low number of donor card signees, and the ban on financial incentives that would shift the locus of decisionmaking away from the patient's bedside to the luncheon table—when a person is well and can consider his or her own future coolly and rationally—all lead to the unhappy reliance on requests to families when they are in the greatest emotional pain. This is a high price indeed for a somewhat abstract ideological point—the noncommoditization of organs and the zealous commitment to values of communitarian uplift through altruism (see Havighurst and King 1986).

In addition to requiring that Medicaid and Medicare hospitals ask families of potential organ donors to consider organ donation for their dead or dying next of kin, the 1986 legislation adopted some other very fundamental, albeit subtle, regulatory policies for organ transplantation. For example, if organ transplantations are performed in a particular hospital, that hospital must be a member and abide by the rules and requirements of the OPTN (i.e., UNOS) in order to participate in Medicaid or Medicare. On the surface, that looks like a relatively innocuous requirement—a hospital in which transplants take place should have access to the privately established, publicly funded network for organ procurement and distribution. After all, Congress had funded this network to provide a measure of private, nongovernmental autonomy in the system of procurement and distribution of organs. Access to that system surely would enhance opportunities for patients, for hospitals, and for organ transplantation programs. It would also provide a more complete database for the research and analysis of clinical evidence (Salvatierra 1988).

As it turns out, the mandatory membership requirement has become a subtle, indirect means for establishing coercive regulation. No hospital seeking to maintain its eligibility for Medicaid or Medicare participation can permit organ transplantation unless the hospital and all its transplantation programs meet UNOS's membership criteria. UNOS took advantage of the statutory requirement for transplant hospital membership by establishing restrictive membership standards. To qualify for membership in UNOS, a transplant program must satisfy a detailed set of requirements, which include guidelines regarding staffing patterns; personnel qualifications, survival rates, and facilities. Once a member of UNOS, a hospital must abide by UNOS rules and requirements or face disqualification from Medicaid or Medicare participation. Thus, instead of serving as a publicly funded resource for improving efficiency of the procurement and distribution system, UNOS took on the role of a nongovernmental or quasi-governmental regulatory body. This was the vision of the national Task Force on Organ Transplantation—that there be a unified national system for organ procurement and allocation (U.S. DHHS 1986).

The rationale for the UNOS standards is quality control. As DHHS has put it, "the purpose for [UNOS's] membership rules is to serve as a proxy for quality."[33] DHHS acknowledged that some of UNOS's requirements are more stringent than DHHS's conditions for a transplant center's eligibility for Medicare participation.[34] If a transplant program meets DHHS criteria for payment under Medicare, it (and the entire hospital of which it is a part) would nevertheless lose eligibility for Medicare participation if the transplant program failed to comply with UNOS standards.

UNOS bylaws (1987: sections 1.2, 2) require that all transplant programs of a transplant center come into "full compliance with all UNOS membership criteria." If UNOS approval of a transplant program is not secured, a transplant center must "not perform any further transplant of the applicable organ until after it has established full compliance to the satisfaction of . . . UNOS" (ibid.). Thus, a hospital with an organ transplantation program that does not satisfy UNOS's membership criteria is for all practical purposes not able to continue its transplantation program at all. It is not just a question of a hospital foregoing access to the UNOS network, or even foregoing access to Medicare or Medicaid payment for transplantation (in circumstances in which such financial support would be available). The stakes are much steeper. Unless a hospital drops its non-UNOS-qualifying transplantation programs entirely, the hospital would be obliged to "forego Medicare and Medicaid payment for *all* services, not just transplant services."[35]

The statutory requirement that hospitals with transplant programs participate in and abide by the rules and requirements of the network gives an enormous amount of regulatory power to UNOS, which is unconstrained by the limitations placed on governmental power established under the Administrative Procedures Act. From comments disclosed by DHHS, "there is a widespread perception that UNOS requirements are unfair" and that, as with proposed governmental regulations, proposed changes in UNOS guidelines should be "open to public comment."[36] DHHS responded to those comments by negotiating with UNOS to allow for provisional membership for transplant centers that do not meet all UNOS requirements for full membership and to require UNOS to establish a satisfactory conflict resolution process.[37] Yet the DHHS contract with UNOS permits UNOS to set restrictive membership and program certification policies, which have the effect of law because of the requirement that Medicare and Medicaid hospitals with transplantation programs be members of and abide by the policies of UNOS.

DHHS has readily acknowledged that hospitals wishing to participate in Medicaid and Medicare must "discontinue transplant programs that do not meet

33. 53 Fed. Reg. 6526, 6528 (1988).
34. *Id.* at 6529.
35. *Id.* at 6526, 6529, 6530.
36. *Id.* at 6529.
37. *Id.*

UNOS's requirements."[38] Thus, as DHHS expressly acknowledged in response to comments on its proposed regulations, "if a hospital has multiple organ transplant programs, it must meet Network criteria for all programs or immediately terminate any program that does not meet UNOS membership criteria in order for the hospital to continue participation in the Medicare and Medicaid programs."[39] DHHS expressed its belief that such an outcome "represents a significant barrier to market entry" and could have a "significant adverse effect on competition."[36] The department concluded that those anticompetitive effects were not the result of its proposed regulations but stemmed from the 1986 statute that dictated that Medicaid and Medicare participation for a transplant hospital depended on meeting transplant requirements of the network. DHHS also concluded that the regulations would have only a "slight impact on hospitals" because "all transplant centers are accredited by the JCAHO, which already requires hospitals to participate in the Network."[40] These statements by DHHS are only partly correct, however.

It is true that the 1986 legislation requires transplant hospitals to satisfy OPTN requirements if they wish to participate in Medicare and Medicaid. Similarly, JCAHO accreditation standards may compel hospitals seeking accreditation to participate in the OPTN. While these observations are correct, they are also largely beside the point. Membership in the OPTN need not be anticompetitive. The effect of membership on competition turns entirely on the nature of the membership requirements established and enforced by UNOS. It is the substance of the rules governing membership, not the membership requirements themselves, that determines whether there will be a significant adverse effect on competition. It is also likely that the substance of the network rules that will govern any potential antitrust analysis of the anticompetitive impact of exclusionary network guidelines.

The nature of the UNOS membership rules, in turn, derives from the conceptualization (i.e., the ideology) that UNOS and DHHS adopt for the role of the OPTN. There is, in this regard, an essential similarity to the conceptualization of health planning and its relation to competition. One view suggests that health planning is fundamentally at odds with competition. Needs and goals are centrally determined in a political and technocratic fashion; planners seek to influence or even control resource allocation decisions (e.g., through "rationing"). That vision of health planning "manifestly is designed to substitute for the market in the allocation of resources. . . . Resource allocation decisions are centralized and politicized. Attention to developing appropriate institutions for democratic decisionmaking substitutes for attention to the proper functioning of an economic marketplace" (Blumstein 1988b).

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38. *Id.* at 6546.
39. *Id.* at 6530.
40. *Id.*

While the market-substitution vision of health planning may be incompatible with a more decentralized, pluralistic, market-oriented system, the central planning approach is not the only option available. Market-enhancing roles for planning are possible: "For example, planners can collect and disseminate information. . . . Planners can also gather and evaluate . . . data and . . . contribute to the measurement and disclosure of assessments of indicia of quality. . . . Planners could maintain a vigil against restraints of trade, and they could identify and recommend the elimination of public or private barriers to . . . efficient medical care delivery" (Blumstein 1988a). Thus, in the health planning context, a great deal turns on one's vision of what health planning is and what its proper role should be:

> Is it to be viewed as a comprehensive, top-down method of resource allocation designed to substitute a politically driven command-and-control bureaucratic system, which blends technocratic expertise and interest-group negotiation, for the resource allocation decisions of decentralized decisionmakers in a functioning market? Or is it to be viewed as a means of facilitating competition by providing technical assistance and independent analysis to participants in the market process? (ibid.: 39).

The analogy from health planning to UNOS is quite close. If UNOS is to resemble a comprehensive, top-down system for determining the best way to perform transplants and to procure and distribute organs, then a tight regulatory approach might well follow as a logical strategy. If, however, there is a desire to maintain a flexible, decentralized system of transplantation and organ procurement and distribution, a very different approach would be appropriate. The top-down regulatory approach, obviously, would have a much more substantial impact on competition—and possibly on other values such as breadth of access (Bovbjerg forthcoming). It also would trench on values associated with and protected by antitrust laws.

The next question to be addressed, then, is whether DHHS could have chosen the more flexible, decentralized, pluralistic system for the OPTN, or whether it was constrained—as it claimed—to select the regulatory approach by controlling legislation. This inquiry is important for two critical reasons. First, it addresses the question whether DHHS has flexibility to alter the existing vision of the OPTN through exercise of administrative oversight; second, it influences the antitrust analysis which asks whether Congress has intended to nullify the application of the antitrust laws in this arena.

Careful analysis of the governing legislation reveals that DHHS had and still has a great deal of freedom to choose among competing visions for the OPTN. Either it failed to understand properly the competing visions for the OPTN, or it misread the requirements of existing law. That misreading could have been a handy mechanism by which proponents of one viewpoint effectively shut off serious consideration of the concerns clearly expressed about the impact of the UNOS reg-

ulations on competition and other values associated with pluralism and decentralization.

The National Organ Transplantation Act of 1984 required DHHS to contract with a private nonprofit entity to establish and operate a network that would set up a registry of patients in need of organs and a national system for matching organs and individuals. The network was to "assist organ procurement organizations in the distribution of organs which cannot be placed" locally, develop standards of quality for organs used in the network, and coordinate the transportation of organs from procurement organizations to transplant centers.[41] Nothing in the 1984 statute or its legislative history mandates the kind of restrictive, exclusionary authority that UNOS now has and that its contract with DHHS apparently sanctions. Nothing in the 1984 statute or its legislative history suggests that the system developed by the network must be exclusive. On the contrary, the rationale for the network seemed to be that of a facilitator, a useful tool for improving transplantation center efficiency and effectiveness.

Indeed, the 1984 act has distinct elements of a market-perfecting orientation—a network to match organs more efficiently, to reduce the number of wasted organs, to facilitate transportation, and to educate physicians by making available information and analyses of data regarding organ transplantation. That is a function compatible with a pluralistic, decentralized, voluntary system. It is a far different role than the nongovernmental or quasi-governmental regulatory role now played by UNOS in virtually every facet of organ transplantation—organ procurement, organ distribution, and the actual details of the transplantation procedure itself.

In sum, there is nothing in the 1984 legislation that would require DHHS to choose a highly regulatory model for the OPTN. The selection of models is a matter of DHHS discretion. DHHS's exercise of discretion, in turn, must be gauged by the substantive policies adopted and implemented by the OPTN. DHHS cannot distance itself from the policies of the OPTN but must take responsibility for those policies. Once membership in the OPTN became mandatory, the case for autonomy of the OPTN became much less compelling, as the federal government effectively was regulating by delegating authority to UNOS, the OPTN contractor. Oversight through the OPTN contract is possible and, given the coercive effect of OPTN rules and regulations, clearly necessary. It may even be constitutionally required under cases limiting the ability of the federal government to delegate lawmaking or rulemaking authority to private, self-interested persons or groups.[42] In any event, as will be discussed below, the fact that neither the 1984 nor the 1986 legislation mandates a particular vision for the OPTN leaves open the substantial likelihood that restrictive or otherwise anticompetitive conduct by UNOS will be subject to the scrutiny of the antitrust laws.

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41. 42 U.S.C. § 274(b)(2) (1982).

42. A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935); Eubank v. Richmond, 226 U.S. 137 (1912).

UNOS policies. UNOS has established an elaborate set of rules and regulations guiding standards for membership. Institutional members, as defined in the UNOS articles of incorporation, must be "active in the field of human organ transplantation" and be either a transplant center, an independent organ procurement agency (IOPA) which serves two or more transplant centers within its service area, or an independent tissue-typing laboratory (ITTL) which serves two or more centers within its service area (UNOS 1987). The bylaws further provide for nonvoting institutional memberships for IOPAs and ITTLs serving only one UNOS member transplant center within their service area. Although the term for institutional members of UNOS is indefinite, failure by institutional members to conform with UNOS standards or performance levels can result in termination of membership.

The core of UNOS is its policies and standards for membership. No distinctions are drawn between membership and participation in UNOS and in the OPTN, which UNOS operates under contract with DHHS. Although this is not a requirement of federal statutory law, or even of DHHS regulatory policy, for all practical purposes UNOS and the OPTN are functionally identical.[43]

The organizational culture behind the UNOS policies and guidelines clearly reflects an intellectual debt to the recommendations of the national Task Force on Organ Transplantation. In a relatively recent statement of policy, UNOS clearly regarded the task force's recommendations as the basis upon which its own policies have been based. For example, UNOS noted the task force recommendation "that a single national system for organ sharing be established; that its participants agree on and adopt uniform policies and standards by which all will abide" (UNOS 1988: 6). Adhering to the task force report, UNOS has stated that "the effectiveness of the national network would depend on the development of uniform standards and policies that all participants agree to follow" (ibid.: 6). The role of UNOS, as envisioned by its leadership, seems to be the establishment and enforcement of uniform standards of organ allocation that should be followed by all procurement agencies and transplant centers (ibid.: 10). UNOS is charged, in that view, with responsibility for developing the standards that will control all facets of the organ transplantation process. Its structure will be appropriately representative of a variety of constituencies, but within that political framework, UNOS will write the tune and its members will dance to the music or pay the price—discontinuance of organ transplantation or excommunication from all participation in Medicaid or Medicare.

Quite clearly, UNOS has embraced the top-down, command-and-control regulatory vision of its role. This is compatible with the suspicion of pluralism and

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43. Whether the identity of UNOS and the OPTN should be retained is questionable. UNOS, as an organization, can have membership rules and regulations appropriate to its voluntary purposes. Membership in the OPTN is mandatory for Medicare/Medicaid hospitals. Because of this coercive, regulatory status, and because of antitrust policy concerns, the OPTN should be governed by less restrictive membership rules and regulations than UNOS.

decentralization underlying the task force's report. As demonstrated earlier, under the applicable statutes DHHS has the ability to alter this conception of UNOS's role—to bring UNOS policies into conformity with a very different approach toward the proper role of the OPTN. Indeed, the contract with UNOS provided (and continues to provide) DHHS with leverage over UNOS policies, a power DHHS apparently has chosen to exercise only modestly.[44] As a result, at a time when health policy has increasingly followed the tune of pluralism and competition, organ transplantation policy, with DHHS complicity, has been marching to the beat of a very different drummer—centralized, bureaucratic decisionmaking. Despite DHHS protestations to the contrary, this outcome, which is at odds with the Reagan administration's professed belief in pluralism and decentralization, is not mandated by federal statutory law. Federal law permitted this result by establishing a private sector network and then in effect mandating transplant center membership in the network. The private network—UNOS—has embraced the conception of its role embodied in the federal task force report. By controlling the contracting specifications and rulemaking process, however, DHHS had (and still has) the authority and the power to reshape the network in accordance with a very different vision of its proper and properly delimited role.

In this section I will focus on three areas of UNOS regulatory standards and criteria: IOPA membership, transplant program membership, and organ acquisition and distribution.

IOPAs. UNOS established detailed guidelines for IOPAs to assure the smooth functioning of the organ procurement process. For example, an IOPA must maintain the potential organ donor, document an array of laboratory results (designed to ensure organ procurement quality), and secure and document appropriate consent for organ donation. UNOS requires that an IOPA have agreements with regional transplant centers designating the IOPA as a procurement agency. UNOS also specifies minimum personnel requirements for an IOPA. One interesting criterion, which appears to conflict with subsequently adopted DHHS regulations, is that an IOPA must have a defined exclusive service area. The 1986 legislation specifically states that DHHS "may not designate more than one organ procurement organization for each service area."[45] This was a response to the federal task force recommendation that competition among organ procurement agencies be discouraged. DHHS has recognized that this requirement will inevitably reduce the number of OPOs qualified to participate in Medicare.[46] In part to alleviate this potential problem, DHHS regulations expressly permit transplant hospitals to deal with any designated OPO they wish.[47] DHHS requires one OPO per service area, but it does not give any OPO a monopoly within its service area. Transplant hos-

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44. There is some evidence that DHHS now sees the issue and is in the process of an internal debate on the proper oversight relationship between DHHS and the OPTN (Health Policy Week 1988).

45. Pub. L. No. 99-509, § 9318; Social Security Act § 1138 (b)(2) (1986).

46. 53 Fed. Reg. 6546 (1988).

47. *Id.* at 6541.

pitals are free to work with a number of OPOs from a range of geographic areas. This is an example of DHHS's sensitivity to the anticompetitive consequences of an exclusive, monolithic system that bars entry and otherwise precludes the stimulus to performance that typically results from competition.

Thus, the UNOS requirement that an IOPA have a "defined exclusive service area" is puzzling and troublesome. To be qualified for DHHS designation, an OPO must be a member of UNOS. DHHS has stated its position that OPOs should not have exclusive territorial rights. If the UNOS requirement should be interpreted to be in conflict with the DHHS regulation, then by enforcing its rule to deny membership to an IOPA, UNOS would be in a position to overturn the policy of the federal agency charged with administering the federal organ transplantation policy. If this is permitted (as DHHS suggests),[48] then UNOS, as a private organization, would be in a position to override policies established by the federal government itself—a remarkable outcome that demonstrates the awesome potential power vested in UNOS. In this example, it would allow the centralized, bureaucratic ideology of the task force report and of UNOS to supersede the attempted accommodation of competition adopted by DHHS in its regulations.[49]

Transplant programs. To qualify for UNOS membership, a transplant program must meet specific, detailed requirements, particularly concerning personnel. This is apparently a response to the task force recommendation that "transplant centers be designated by an explicit, formal process using well-defined, published criteria" (U.S. DHHS 1986: 113).

In some details, the UNOS personnel criteria differ from DHHS criteria for approving Medicare transplant programs, especially for kidney transplants, which are paid for by Medicare. The tougher UNOS standards have the effect of barring federal payment to transplant centers not meeting UNOS standards—even if they meet DHHS standards. Moreover, a transplant center's failure to comply with the Medicare designation standards has the effect only of barring federal payment for otherwise eligible transplants in the noncomplying centers. Hospitals are allowed to develop transplant protocols at odds with Medicare regulations and either seek payment from other sources or subsidize them internally through other available funds. The cost of noncompliance is transplant-specific and would allow noncomplying hospitals to experiment on their own without an adverse effect on their other operations.

On the other hand, a transplant center's nonadherence to UNOS policies has much more far-reaching consequences. The failure of any transplant program to

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48. *Id.* at 6529, 6530.

49. Concern about this potential for vesting excessive power in private hands has been voiced by Senator Orrin Hatch, an original sponsor of the 1984 organ transplantation legislation. Hatch has expressed the view that the delegation of regulatory authority to UNOS is unconstitutional. Relying on A.L.A. Schechter Poultry Corp. v. United States, *supra* note 42, Hatch argued that Congress cannot delegate regulatory authority to a private entity. According to Hatch, the delegation to UNOS is particularly troublesome because the UNOS "guidelines take effect without any affirmative action by the executive." Congressional Record—Senate, 17 June 1988, at 58093–95.

comply with UNOS policies means the debarment of an entire hospital from Medicare or Medicaid participation. In substance, this means that no hospital will be able to strike out on its own with regard to organ transplantation unless it secures UNOS authorization. Even if DHHS guidelines are satisfied or if DHHS might otherwise approve (or not disapprove) of a transplant program, no venture that does not conform to UNOS can be undertaken without jeopardizing an entire hospital's Medicare/Medicaid participation. This poses a staggering potential problem regarding entry barriers and resistance to innovation—especially when the existing transplant establishment is entrusted with such enormous control to impose clinical orthodoxy on the potential heretic.

DHHS has acknowledged the implicit supremacy of UNOS in circumstances where UNOS guidelines conflict with DHHS policies: federal law "does not require the Network's [i.e., UNOS's] rules to be identical to those under Medicare."[50] As a result, where there are differences, the practical consequence is that UNOS criteria prevail—thus potentially reducing the number of eligible transplant centers.

The task force report asserted that "authority . . . for [transplant] center designation should reside within DHHS" (U.S. DHHS 1986: 115). Subsequent to the task force report, DHHS adopted a designated center approach for Medicare payment for heart transplantation, reflecting an extrapolation of its authority to designate kidney transplant centers. The question is whether DHHS designation or nondesignation decisions should be permitted, under the DHHS contract with UNOS, to be superseded by potentially conflicting UNOS designation standards. Although federal law may not require that UNOS and Medicare rules be identical, as DHHS asserts, surely DHHS has ample authority to require UNOS to defer to Medicare rules where conflicts exist.

An example of the potential for restrictiveness of UNOS policies is the limited opportunity for new transplant programs to come on stream. An "established transplant program in one organ" seeking to start a transplant program in another organ may be granted two years to comply with all the UNOS standards, but transplant programs being started without a sufficient background in the transplantation of another organ must meet all UNOS criteria from the outset. (UNOS defines an "established transplant program" as one that has performed 50 or more transplants in a specific organ and has been in operation for at least two years.)

That type of entry barrier clearly tilts toward preserving the transplant "territory" of preexisting transplant programs. It should prima facie make any marketeer apprehensive, particularly since such restrictiveness is being imposed on potential entrants by entrenched interests that could be threatened by the development of new, competitive programs. In other contexts, the antitrust laws have been invoked to scrutinize such arrangements carefully.

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50. 53 Fed. Reg. 6530 (1988).

The historical evolution of this policy should provide little comfort in this regard. In its November 1987 bylaws, UNOS allowed new transplant programs not started by an "established transplant program" to come into existence if UNOS criteria were satisfied at the outset "except for survival criteria, which will be evaluated for compliance two years after the start of the program." Under the May 1988 bylaws, UNOS requires such new programs to "meet all UNOS membership criteria from the outset." This presumably would include satisfying survival criteria, which are unspecified in the bylaws. Given that a hospital can only have a transplant program if it satisfies UNOS requirements, it is not at all clear how such a new program can be commenced at all outside an "established transplant program"—i.e., how it can immediately demonstrate compliance with UNOS survival rate requirements. This seems extraordinarily restrictive and a significant barrier to entry by programs set up by other than an "established transplant program." The basis for the more restrictive policy adopted between November 1987 and May 1988 is not clear and, given its self-evident anticompetitive character, seems highly suspicious on its face.[51]

Although the rhetoric tends to emphasize quality and access concerns, one need not probe too deeply to see that payers as well as entrenched providers have a potential interest in restricting the number of designated centers to keep overall costs down. Limited availability of facilities (and of organs) may reduce the number of transplants and keep program costs down (Bovbjerg forthcoming). This is quite a different agenda than the one stated as justifying establishment of and support for the OPTN. Given the differences between UNOS and DHHS standards and given the nature and composition of UNOS, a healthy skepticism of the UNOS regulatory provisions and their impact on competition is entirely justified (Sloan, Shayne and Doyle 1989).

Organ acquisition and distribution. Of the various proposals that Congress asked the task force to study,[52] a proposed list of prospective organ donors was the major idea rejected in the task force report. The report did recommend a centralized list of potential recipients, but concluded that a list of potential donors was not useful (U.S. DHHS 1986: 49–51). UNOS has followed the task force's recommendations by establishing and maintaining a computerized list of potential recipients and by declining to establish a potential donor list.

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51. The May 1988 provisions for new programs are more restrictive for an "established transplant program" as well. Under the November 1987 policies, an established program could start a new program in another organ on an unrestricted basis, provided it complied with all UNOS criteria within two years. No regulations restricted the new start-up operation for that interim two-year period. The May 1988 policies are much more restrictive, calling for "conditional approval" for a two-year period but only if the new program satisfies specific "criteria for conditional approval." These concern staffing and compliance with open-ended, potentially ad hoc policies of UNOS's Membership and Professional Standards Committee (MPSC). Thus, a new program, for conditional approval, must comply with "such interim operating policies and procedures as shall be required by" the MPSC—an entirely discretionary standard subject to the potential for abuse, arbitrary application, and anticompetitiveness.

52. Pub. L. No. 98-507, § 101(b)(3)(J) (1984).

The donor list issue is telling for a number of reasons. Advocates for formulating and maintaining such a list argue that it might serve as a stimulus for recruiting potential donors by encouraging the seeking of signees who, left on their own, might not sign a donor card. A potential donor list might therefore increase organ supply. It could help shift the locus of organ solicitation away from the family of the potential donor to the donor himself, and it could also shift the timing of organ solicitation. Moreover—and one may conjecture that this is the real rub—the existence of a potential donor list would provide a handy vehicle for the introduction of incentives. Financial or other incentives might be used to induce potential "donors" to make binding commitments for fixed periods of time to allow their organs to be used for transplantation upon their death.

The resistance to the establishment of a list of potential organ donors is another example of the policy-inhibiting aspects of a set of hard ideological rules—there is no valuable consideration for allowing one's organs to be used after death for transplantation, an exclusive reliance on altruistic motivation for transplantable organ supply, and a total commitment to the purported benefits of communitarian expressions of solidarity through families' choosing to donate the organs of their next of kin at the time of death. The existence of a list of potential donors might cause analysts concerned about transplantable organ supply to consider legalizing inducements for signing up. Whether or not such inducements would be effective in increasing transplantable organ supply is an empirical question; some states apparently have such ideas (e.g., through tax credits) under consideration, although the 1987 revision to the UAGA proposes (on the basis of the most abstract and skimpy reasoning) that all states should ban the purchase or sale of organs from cadavers. Until flexibility exists—that is, until financial inducements are allowed—nobody will know how effective or costly they might be.

The conventional wisdom of opponents is that such financial inducements will not enhance supply (Robertson 1987: 80), but in the absence of evidence it is clear that the opposition stems from ideology, not empiricism. For example, the cursory commentary on Section 10 of the revised UAGA (1987), which proposes the ban on the purchase or sale of cadaveric organs, quotes the recommendation of the task force report that each state should enact laws prohibiting "the sale of organs from cadavers or living donors within their boundaries" (U.S. DHHS 1986: 99). It further quotes a 1985 Hastings Center report, which emphasizes "altruism and a desire to benefit other members of the community" and expresses concern that transplantation "undertaken primarily with an eye toward profit rather than therapy will severely imperil the moral foundations, and thus the efficacy, of the system."

UNOS could contribute modestly by creating a list of potential organ donors and allowing nonpecuniary inducements (such as active appeals to good citizenship) to be tried. That approach would shift the timing and locus of decisionmaking and perhaps provide some basis and impetus for encouraging legalization of experiments with solicitation or sign-up inducements. Also, with greater evidence of a donor's public commitment to organ donation, the culture of transplantation

centers might change to allow sign-ups on such a donor list to be deemed sufficient to allow organ harvesting without further involvement of or imposition on next of kin at the bedside. After all, under existing law, any person of sound mind who is 18 years of age or over can donate his organs for transplantation, and anyone who acts in good faith in accord with the UAGA is immune from civil liability or criminal prosecution. The 1987 revised UAGA goes even further in this direction, expressly stating that "an anatomical gift that is not revoked by the donor . . . does not require the consent or concurrence of any other person after the death of the donor" (National Conference 1987: section 2b).

Yet, on ideological grounds opponents of a donor registry seem to object even to the shift of decisionmaking locus and timing to what surely is a more rational, compassionate setting—i.e., prior to any life-threatening episode. There seems to be in the transplant orthodoxy a rejection of this shift because it would change emphasis away from "next-of-kin consent," thereby depriving the family of an opportunity for "promoting a sense of community through acts of generosity" (U.S. DHHS 1986: 28). This strong philosophical stance, which is implicitly embodied in the UNOS requirement of consent by the next of kin, is out of sync with the legal position of the 1987 revisions to the UAGA. In short, as the task force report candidly acknowledged, efficiency and lifesaving values need to be balanced against other social values, such as the rather abstract and ethereally romantic "value of social practices that enhance and strengthen altruism and our sense of community" (ibid.: 28). Given the sensitive nature of next-of-kin donation at the time of death and given the questionable efficacy of that approach in terms of organ supply, rigid adherence to this communitarian value seems to be achieved at a high price indeed.

UNOS policies require that all potential recipients of organ transplants be listed on the UNOS computerized waiting list. But UNOS does not establish a monolithic nationwide system. It does not, for example, require that all locally harvested organs be shared regionally or nationally. An individual transplant center may retain the organs it harvests, with two important constraints. First, UNOS requires mandatory regional sharing of all kidneys having a six-antigen match. This kind of tissue typing and matching can improve the likelihood of long-term graft success (ibid.: 67), adding to and enhancing the effects of immunosuppressive drugs such as cyclosporine. Second, UNOS has established a detailed point system for allocating cadaveric kidneys and extrarenal organs. While transplant centers can retain the organs they harvest (other than six-antigen-match kidneys), each center must abide by UNOS allocative criteria in distributing organs within its own institution. Thus, UNOS's explicit criteria control distribution of organs within all member institutions and when organs are shared regionally or nationally.

The requirement for mandatory sharing of six-antigen-match kidneys and the mandatory allocative point systems demonstrate the lack of control organ donors are given over the identity of potential recipients under UNOS policies. The UAGA allows the organ donor to designate a donee, who can be a specific individual.

The 1986 task force report, in contrast, recommended that "donated organs be considered a national resource to be used for the public good" (ibid.: 86). Organs would become socialized, with individual donors stripped of power to control the destiny of their donated organs or to designate specific beneficiaries.

Since every jurisdiction has enacted the UAGA, the task force recommendation would cause a substantial change in the law. UNOS policies, which reflect general agreement with the task force approach in this regard, would indicate that, despite the legal authority conferred on donors by the UAGA, a transplant center could not honor a specific bequest to an individual recipient if that recipient did not have the highest point total under the UNOS point system. Thus, there is at least a potential conflict between the provisions of state law and the ability of transplant centers to comply with state law. Violation of UNOS policies could result in loss of UNOS membership; that, in turn, would render a hospital ineligible for Medicaid and Medicare participation.[53]

It is interesting to speculate what remedy, if any, a frustrated recipient would have in a situation in which a donor had designated that specific recipient as donee but hospitals refused to honor that legally authoritative gift out of fear of violating UNOS policies.[54] Under Section 2(e) of the UAGA, "the rights of the donee created by the gift are paramount to the rights of others." (The 1987 revision retains this provision.) Section 2(c) of the UAGA bars a donee with "actual notice of contrary indications by the decedent" from accepting a gift, and Section 2(b) prohibits next-of-kin donation in opposition to the wishes of the decedent donor. Thus, UNOS policies potentially require transplant center conduct explicitly at odds with and in violation of state law (as reflected by the UAGA).

Would state courts under these circumstances order transplant centers to give effect to authoritative state law, against a hospital's defense that adherence to state law would violate UNOS policies and thereby jeopardize that hospital's continued eligibility for Medicaid and Medicare participation? Would a hospital be able to raise as a successful defense to an after-the-fact liability claim that its refusal to honor an organ bequest to a specific, designated beneficiary was based on its desire to comply with UNOS policies? Although these issues have not been authoritatively litigated, one might reasonably conjecture that state courts might well give effect to controlling state law, which empowers donors and recipients. It is even conceivable that state courts would impose liability on UNOS for its coercive role in compelling transplant centers to dishonor state law. In any event, the potential for conflict between UNOS policies and state law has not yet been played out and, unlike the UAGA, which provides for immunity for those who act in reliance on

53. Whether or not UNOS would expel a member for a single act in which a hospital acceded to the dictates of state law is not the issue. Prudent hospitals will proceed in ways unlikely to challenge the supremacy of UNOS rules, given the stakes involved.

54. This could happen because a donee is not the best match or because the donee is not listed on the waiting list of the hospital where the prospective donor is a patient.

it, no such statutory immunity exists for hospitals acting in reliance on UNOS policies.

It was the federal task force's vision that donated organs be considered a "national resource"—that is, a "scarce public resource" whose distribution should be governed "by criteria based on need, effectiveness, and fairness that are publicly stated and publicly defended" (ibid.: 86). Medical criteria should dictate organ allocation, with the major factors being urgency of need and probability of success (ibid.: 87). According to the task force report, "If two or more patients are equally good candidates for a particular organ according to the medical criteria of need and probability of success, the principle of justice suggests that length of time on the waiting list is the fairest way to make the final selection" (ibid.: 89).

Although it recognized "practical and technical limitations," the task force labeled as "ideal" a system of organ distribution in which geography would be irrelevant (ibid.: 91). The 1984 National Organ Transplant Act identifies one function of OPTN as assisting in the distribution of organs "which cannot be placed within the [OPO's] service areas."[55] The statute seems to assume a preference for a regional orientation, but it is unclear whether that reflects a technocratic judgment as of 1984 or a policy preference.[56] The 1988 amendments to the 1984 act would delete the geographical language in order to "remove any statutory bias" regarding the proper role of geographical factors in organ distribution.[57] The OPTN (UNOS) will resolve issues concerning "fair and effective distribution of organs" with "patient welfare . . . be[ing] the paramount consideration.[58]

The task force's recommended mandatory sharing of organs across transplant centers for perfectly matched donor/recipient pairs (ibid.: 70). It discussed the advantages of organ sharing in other circumstances, but made no other specific recommendation about mandatory sharing. The task force also recommended "a single national system for organ sharing" with "uniform policies and standards by which all will abide" (ibid.: 69). The task force recognized a "diversity of practices" among transplant centers on a wide array of transplantation issues, including patient selection criteria (ibid.: 68), and concluded that uniformity across centers was desirable and, in some contexts, necessary for effective organ sharing.

The organ distribution policies adopted by UNOS follow closely the recommendations of the task force, but they also strike new ground in some areas. UNOS requires sharing of perfectly matched kidneys, but does not mandate sharing of other perfectly matched organs. Voluntarily shared organs are first allocated regionally, then nationally, based on the UNOS point system. Thus, UNOS policies

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55. 42 U.S.C. § 274 (b)(2)(C) (1982).

56. Recent evidence suggests the attractive possibilities for wider distribution of transplantable organs from center to center (Opelz 1988).

57. H. R. Rep. No. 383, 100th Cong., 1st Sess. 7 (1987); S. Rep. No. 310, 100th Cong., 2nd Sess. 14 (1988).

58. 42 U.S.C. § 274(b)(2)(C) (1982).

restrict required sharing and expressly provide for regional preference of voluntarily shared organs.

While transplant centers may therefore retain the organs they procure, all local-level organ distributions must proceed in accordance with the UNOS point system. To the objection of some who advocate a nationally integrated allocation system, UNOS policies expressly permit patients to be listed on multiple local waiting lists. To the extent that organs are not shared regionally or nationally (and therefore remain at the transplant center or other local level), such multiple listings improve a patient's likelihood of being successfully matched at the local level. That provision clearly rewards aggressive patients and transplant center initiatives and offends purist access egalitarian ideologues, who view such patient behavior as improper gaming of the system.

Overall, the task force and UNOS have not pushed the "national resource" concept to the extreme. The medical case for matching seems strong (Opelz 1988), but the task force recommendations and UNOS's policies seem to reflect an accommodation with prevailing views of major transplant centers and their surgical teams that the availability of immunosuppressive drugs such as cyclosporine make sharing less important (Salvatierra 1988). Transplant surgeons have historically felt territorial about organs they harvest, and the UNOS policies appear to reflect a compromise with this prevailing attitude. In light of the task force's strong condemnation of the commercialization of organs and its advocacy position that property rights of donors be eliminated, it is ironic to see that the ideology of organs as a "national resource" must respond to the concept of territoriality or property rights—not of donors or patients, but of transplant centers.

An antitrust perspective on organ transplantation policy

Earlier in this paper I alluded to the potential for antitrust scrutiny of restrictive, anticompetitive UNOS policies. The antitrust laws provide an important mechanism for the enforcement of procompetitive policies and the prohibition of excessive restraints on the competitive ideal. In this section, I will briefly explore applications of potentially relevant antitrust principles and consider whether the existence of the 1984 and 1986 organ transplantation legislation would shield the conduct of UNOS from antitrust scrutiny under principles of implied repeal of the antitrust laws. My conclusion is that the case for implied repeal is not strong and that the antitrust laws will apply to UNOS's conduct.

The Supreme Court has repeatedly acknowledged that "private standard-setting associations have traditionally been objects of antitrust scrutiny."[59] The reason for concern is that "private standard-setting associations . . . include members having

59. Allied Tube & Conduit Corp. v. Indian Head, Inc., 108 S. Ct. 1931, 1937 (1988).

horizontal and vertical business relationships."[60] Thus, such private standard-setting organizations are typically treated as continuing conspiracies of their members (Areeda 1986: 343), who often have economic incentives to restrain competition. "Product standards set by such associations have a serious potential for anticompetitive harm" and are subject to antitrust scrutiny.[61]

The OPTN is potentially subject to antitrust review on at least two bases—as a private standard-setting organization and as an entity in control of an essential facility. Private standard-setting organizations' behavior is not typically deemed per se illegal. The activities of such groups may be justified because they "promulgate safety standards based on the merits of objective expert judgments and through procedures that prevent the standard-setting process from being biased by members with economic interests in stifling product competition."[62] The reason for antitrust deference, however, is that the standards promulgated by these private associations "can have significant procompetitive advantages."[63]

Under antitrust analysis, it is typically inappropriate for courts to take into account alternative values to be balanced against the value of competition. The balancing that occurs in an antitrust "rule of reason" analysis is an investigation into the procompetitive virtues of various ostensible restraints. Antitrust inquiry focuses exclusively on the "challenged restraint's impact on competitive conditions."[64] The function of a rule of reason analysis "is to form a judgment about the competitive significance of the restraint; it is not to decide whether a policy favoring competition is in the public interest, or in the interest of members of the industry."[65] The policy decision in favor of competition has been made by the antitrust law, which "reflects a legislative judgment that . . . competition is the best method of allocating resources in a free market."[66] Arguments about the desirability of procompetitive practices in a particular context are not for courts or for private standard-setting bodies to consider because the procompetitive policy underlying the antitrust law "precludes . . . inquiry into the question whether competition is good or bad."[67] Thus, the Supreme Court has rejected arguments that "the special characteristics of a particular industry" justify anticompetitive arrangements on the grounds that they "will better promote trade and commerce than competition."[68] If a restraint is to be justified under a rule of reason antitrust analy-

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60. *Id.* at 4540.
61. American Society of Mechanical Engineers, Inc. v. Hydrolevel Corp., 456 U.S. 566, 571 (1982); FTC v. Indiana Federation of Dentists, 476 U.S. 447 (1986).
62. Allied Tube & Conduit Corp. v. Indian Head, Inc., 108 S. Ct. 1931, 1937 (1988); see also American Society of Mechanical Engineers, Inc. v. Hydrolevel Corp., 456 U.S. 566, 570–73 (1982).
63. Allied Tube & Conduit Corp. v. Indian Head, Inc., 108 S. Ct. 1931 (1988).
64. National Society of Professional Engineers v. United States, 435 U.S. 679, 688 (1978).
65. *Id.* at 692.
66. *Id.* at 695.
67. *Id.*
68. *Id.* at 689.

sis, those defending the ostensibly anticompetitive conduct must demonstrate an offsetting "countervailing procompetitive virtue."[69]

Under this aspect of antitrust scrutiny, therefore, the standards promulgated by the OPTN (i.e., UNOS) must receive their justification by their procompetitive character. To the extent that such standards are set without empirical support (Sloan, Shayne and Doyle 1989), the procompetitive rationale for their existence diminishes and, in the antitrust balancing process (the "rule of reason"), such restrictive practices may succumb. Moreover, to the extent that the OPTN seeks "to *enforce* (rather than just agree upon) private product standards," it faces "more rigorous antitrust scrutiny."[70]

In pursuing a command-and-control regulatory approach—in which it seeks not only to establish but also to enforce standards on all facets of the transplantation enterprise—the OPTN runs the risk of more intense antitrust scrutiny. And since, within the framework of antitrust law, OPTN rules and regulations must be justified by reference to procompetitive values, it is not for UNOS to determine that competition is inappropriate in this arena.

The second avenue of potential antitrust scrutiny stems from the OPTN's exclusive control over transplantation activities—a status enforced by the requirement of Section 1138(c)(1)(B) that a hospital with a transplant program must be a member of and abide by the rules of the OPTN if it wishes to participate in Medicare or Medicaid. The "essential facilities" doctrine requires close antitrust scrutiny where potential competitors control and exclude others from access to a facility, service, or resource that is necessary to allow competition to flourish (Blumstein and Calvani 1978).

UNOS rules bar UNOS members from listing patients for a non-UNOS transplant program. UNOS does not allow access to its computer system for matching purposes to non-UNOS OPOs. Non-UNOS transplant centers (if any should exist) cannot obtain organs from UNOS. And patients in non-UNOS institutions may not be listed on the UNOS computer; only UNOS members may place a patient's name on the waiting list. When combined with the mandatory UNOS membership for hospitals' Medicare/Medicaid participation, these exclusionary policies reinforce the exclusive power of UNOS over all facets of organ transplantation. Under governing antitrust law, there is a serious issue whether this aspect of the UNOS enterprise may constitute an antitrust violation—and in this regard, there may even be a case for applying not the balancing rule of reason analysis but the draconian rule of per se invalidity.[71]

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69. FTC v. Indiana Federation of Dentists, 476 U.S. 447 (1986).

70. Allied Tube & Conduit Corp. v. Indian Head, Inc., 108 S. Ct. 1931, 1937 n. 6 (1988) (emphasis in original); see Radiant Burners, Inc. v. Peoples Gas Light & Coke Co., 364 U.S. 656, 659–60 (1961); Fashion Originators Guild of America, Inc. v. FTC, 312 U.S. 457 (1941).

71. See Northwest Wholesale Stationers, Inc. v. Pacific Stationery and Printing Co., 105 S. Ct. 2613, 2619–21 (1985).

The foregoing assumes that the antitrust laws are applicable, as adapted to the context of organ transplantation policy. It is possible to argue, as UNOS has done, that the antitrust laws should have no application to the conduct of UNOS and the OPTN. Any claim of immunity from coverage under the antitrust laws must come from either an express statutory exemption or from an implied or inferred immunity.

The express immunity from the antitrust laws for certain good faith professional peer review activities contained in the Health Care Quality Improvement Act (1986) is an example of an explicit immunity. There is no such explicit immunity from the antitrust laws contained in any of the organ transplantation legislation. Therefore, any immunity from coverage under the antitrust laws must come from an implied immunity. But "the Supreme Court has been very reluctant to imply such a waiver, and it is very unlikely that UNOS would qualify."[72]

Implicit repeal of the antitrust laws is not lightly inferred, and it is questionable whether anything in either the 1984 National Organ Transplant Act or the 1986 budget reconciliation legislation would be construed to immunize UNOS from antitrust scrutiny.[73] As the Supreme Court has stated, the antitrust laws are implicitly repealed only if a subsequent federal statutory scheme is "clearly repugnant" to the ongoing validity and application of the antitrust laws.[74] Implied repeal is found only when there is an irreconcilable conflict between the antitrust law and other federal statutory policy—where "operation of the one makes impossible operation of the other" (Calvani and Gee 1988).

Clearly, there is no irreconcilable conflict between the organ transplantation legislation and the antitrust law. The OPTN surely could have achieved its task without imposing the coercive anticompetitive restraints it did. Since adherence to the 1984 and 1986 legislation self-evidently does not require "breaking" the antitrust law (ibid.), the antitrust law remains applicable to the activities of UNOS.

Conclusion

To some in the organ transplant community, consideration of antitrust issues may well seem like heresy. It certainly brings into perspective the antitrust value of promoting competition—a value frowned upon by the federal task force report. The antitrust philosophy—and its potential application to the organ transplantation context—highlight the fundamental role of a divergent ideology in the evolution of organ transplantation policy.

There is already evidence that courts are applying traditional doctrines designed to protect commerce to the organ transplant arena. For example, the Philadelphia organ procurement agency was barred from pursuing its activities in New Jersey

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72. Speech of Orrin Hatch, Congressional Record (Senate), 17 June 1988, pp. S8093–95.

73. National Gerimedical Hospital and Gerontology Center v. Blue Cross of Kansas City, 452 U.S. 378 (1981).

74. Silver v. New York Stock Exchange, 373 U.S. 341 (1963).

by action of the state of New Jersey. The Philadelphia agency brought suit against New Jersey in federal court, claiming that New Jersey's action was economic protectionism. New Jersey was preserving the market in organ procurement for New Jersey procurement organizations, and by doing so was unconstitutionally interfering with and discriminating against interstate commerce.[75]

The consideration of antitrust and commerce clause doctrine is useful because it brings into sharp focus the widely disparate ideologies that have developed in the area of organ transplantation in contrast to both nonhealth fields and, more recently, the nontransplantation portions of the health industry itself (Greenberg 1988). The federal organ transplantation policy superstructure—as envisioned by the task force report—reflects intense hostility to pluralism, decentralized decisionmaking, profit-making, commercialization, competition, private choice, and even private property (as reflected in one's control of the disposition of one's own organs and one's ability to buy or sell organs). It may well be that the organ transplantation enterprise has peculiar characteristics that warrant some degree of specialized policy prescription. But the field currently suffers from ideological "hardening of the arteries." In other facets of health policy, the emerging consensus has been to require advocates for deviations from competitive norms and decentralized pluralism to bear a burden of justification—and to narrowly tailor proposed deviations to cure specific, delimited market failures (Blumstein and Sloan 1978). The organ transplantation enterprise has indulged in an excess of romanticism, mandating altruism and communitarianism possibly at the expense of saving lives. This ideology has resulted in nonadherence to the private property rights approach toward organ donation of the UAGA, legally adopted in all fifty states. And ideology has resulted in romantic glorification of the symbolic act of next of kin donation of organs from the family members' dying relative, at the cost of a more rational (and compassionate) shifting of the timing of decisionmaking to an earlier stage, where potential "donors" (and with the lure of financial inducements) could confront their own mortality, self-interest, and altruistic desire for helping others in a more relaxed setting.

The existing orthodoxy in the transplant community has not been mandated in any way by federal law. The 1984 legislation called for the creation of a voluntary network to provide an array of facilitative roles. Hospital participation in the network became mandatory as a condition for Medicare/Medicaid participation by legislation enacted in 1986. Nothing in the legislation dictated the type of structure the OPTN should adopt, although DHHS apparently viewed the 1986 legislation as mandating a certain type of network. But DHHS should have given careful consideration to the nature of the OPTN, once its nature shifted from that of a voluntary to a mandatory body. The policy implications of the regulatory power conferred on the OPTN apparently were never fully aired within DHHS. Pro-

75. Delaware Valley Transplant Program v. Coye, 678 F. Supp. 479 (D.N.J. 1988).

ponents of a comprehensive, top-down, coercive system used the enhanced regulatory clout as a covert vehicle for imposing their regulatory agenda. Other models for the OPTN were apparently not seriously considered within DHHS, and no real reassessment of the role of the OPTN took place once it received coercive regulatory powers. Moreover, for advocates of such an approach, private sector rulemaking had the benefit of removing the substance of the regulatory rules from political control. Private sector autonomy could be used as a battle cry for allowing private regulatory behavior to take place free from political control—and even to supersede conflicting DHHS policies.

At present, the issue of the relationship between the OPTN and DHHS is beginning to receive attention, although the scope of discussion is not altogether clear (Pierce 1988). What is clear is that the ideological orthodoxy of the task force report reflects the current culture in the organ transplant community. Advocates of that viewpoint can use the vehicle of the OPTN to establish its hegemony. State law, however, still provides for donor control of organs; it does not view organs as a community resource. State law may also develop to allow some notion of property protection for body parts.[76] Federal law surely allows DHHS ample flexibility in imposing a much-altered vision of the role of the OPTN. Federal antitrust laws likely will be found applicable as a restraint on UNOS/OPTN conduct. The issue could arise either as a result of a private action by a disappointed or disaffected entity, or through aggressive enforcement oversight by an appropriate federal agency. Constitutional restraints on the ability of government to delegate coercive regulatory authority to private standard-setting entities may even require a much more direct supervisory role for DHHS.[77]

The evolution and development of federal organ transplantation policy has involved and been influenced by a relatively narrow band of professional participants. As a result, the policy seems out of sync with prevailing policy evolution in other parts of the health policy arena. It is time for a fundamental reassessment and reappraisal of the entire nature and direction of federal organ transplantation policy—a reevaluation of the constraints on policy imposed by rigid adherence to ideology.

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The Organization of Organ Procurement

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Abstract. The American organ procurement system has improved and matured in the last five years. At the same time, the basic challenges facing it have remained substantially the same because the moral and legal framework of the system has not changed. Success at organ procurement continues to depend on the voluntary cooperation of medical professionals and the families of potential organ donors. The generosity of the American public is so great that the primary challenge facing organ procurement agencies is obtaining cooperation from hospitals and medical professionals. This calls for a "marketing" orientation aimed at those hospitals and professionals who are most likely to treat potential donors. The last five years have seen a more general acceptance of this appreciation of the central task of organ procurement. As a result, the overall effectiveness of the system has improved, as measured by the number of organs procured on a per capita basis and by the number of multiorgan donors obtained. Much of this improvement can be attributed to the diffusion of organizational techniques and approaches, and this diffusion has been encouraged by the involvement of national organizations and public bodies in the organ procurement community. The system remains uneven in its effectiveness and further improvement is possible. It is also possible that the next general round of improvement will result from the application of businesslike information management and marketing techniques.

The organ procurement system is undergoing a multidimensional process of change. First, there have been changes in scale; as little as five years ago, the industry was less than half its present size. Second, the number of transplantation "product lines" has increased. Five years ago, only kidneys were transplanted; now, transplants of hearts and livers are virtually routine, transplants of pancreata and heart/lungs are hardly unusual, and transplants of heart valves and bone are increasingly common. Third, the system has undergone a process of learning and maturation. The last years have seen important changes in the organizational structure of organ procurement agencies (OPAs) and in their operational styles and emphasis, with successful models being widely emulated. Finally, the organizational environment of organ procurement has changed, with a shift from an unorganized, even anarchic, system of local OPAs to increasing oversight and regulation by public and quasi-public bodies.

In other ways, organ procurement has not changed at all. As a moral enterprise it remains a mechanism for giving reality to altruism. On a more mundane level, the "core technology" of the enterprise also remains unchanged. Doctors and nurses must be lobbied, families persuaded, donors maintained, operating rooms obtained, and organs distributed. Like its moral underpinnings, the production function of organ procurement has been constant. Although change in the organ procurement system is a theme of this article, it should not obscure the equally important areas of the system that have remained constant.

Organ procurement agencies

Much of this article deals with the behavior of OPAs. There are presently 71 such agencies operating in the United States (Commerce Clearing House 1988b) and they are responsible for the procurement of all cadaveric human organs. All OPAs are nonprofit organizations or are part of nonprofit hospitals. Under present federal rules, each agency is certified by the Health Care Financing Administration and its service area is clearly defined. With minor exceptions, every part of the United States is served by an OPA (Modern Healthcare 1988). Although some of these agencies are twenty years old, all effectively owe their existence to the end-stage renal disease (ESRD) program passed as part of the Medicare system in 1972.

Under the ESRD program, the federal government pays for the treatment of virtually all Americans who suffer from renal failure. Ninety percent of those covered receive some form of dialysis treatment, but 8,000–10,000 a year receive kidney transplants (Health Care Financing Administration 1986). The costs of the transplant are covered at the same rate and under the same terms as other medical expenses of Medicare-eligible individuals (except that outpatient immunosuppressive drugs are also covered; see Commerce Clearing House 1987). The costs of organ procurement, however, are not reimbursed under the DRG system but are 100 percent cost-reimbursed to OPAs. Medicare has thus been the main source of financing for OPAs since passage of the ESRD law in 1972. With the rapid increase in the number of nonrenal transplants, the financing of OPAs has changed somewhat because these procedures are often covered by private insurance. But kidney transplants continue to represent about 80 percent of all organ transplants, so federal monies continue to provide the bulk of OPA revenue (Rettig 1989).

The organ procurement system is organized along typically American—that is, pluralistic—lines. The money comes mainly from government funds and is spent for government purposes. A kidney transplant is a good investment for the ESRD program because it is a more cost-effective treatment than dialysis; a large number of former dialysis patients have received transplants, much to the government's financial advantage (Eggers 1988). At the same time, the organ procurement agencies are private nonprofit organizations, organized and run at the local level. While these agencies differ greatly in size and administrative structure (Public Health

Service 1987), each is effectively under the overall direction of the transplant surgeons in the community in which they operate. The actual work of organ procurement is done by nonphysicians employed by these agencies. Although many of the transplant or procurement coordinators are nurses, their primary tasks are not medical in nature; rather, their work entails persuading those who control access to potential donors to share information and facilitate the access of OPAs to those potential donors.

In the pages that follow, I will discuss the processes that make up the tasks of OPAs, the way the organ procurement system has changed over the last five years, and how the organizational changes relate to changes in the success of the organ procurement system in providing the raw material that makes the transplantation of human organs more than a mere technical possibility.

The production function of organ procurement

Most transplantable organs come from cadavers, and the percentage is increasing. In 1982, about 69 percent of kidney transplants used an organ from a cadaver; in 1986, that figure rose to 79 percent (Health Care Financing Administration 1986). Of course, all hearts and livers for transplantation must come from dead donors. The term "organ procurement system" usually refers to the system of cadaveric procurement. Finding and screening living organ donors involves personnel, tasks, and ethical considerations quite different from those involved in cadaveric donation (Simmons 1977). Since our concern in this paper is the procurement of organs from the dead, the discussion that follows will employ this usage.

Organ donors must be otherwise healthy individuals who have suffered sudden and fatal trauma to the central nervous system. In practice, most donors are young and have been killed in accidents—usually motor vehicle accidents (Bart et al. 1981a, 1981b). All organ donors must have died in a hospital, because for their organs to be usable they must be maintained on a respirator after brain death has occurred. Because of the nature of injuries leading to brain death and the need to diagnose brain death itself, a neurophysician is generally involved in the care of potential organ donors. Most organ donors die within 48 hours of admission to the hospital and most are in intensive care units (ICUs) when they die (Prottas and Batten 1987). The nursing staff of the ICU is key to the procurement process; they are involved in patient treatment, know the families of donors, and implement the procedures used to maintain the viability of donor organs after the patient has been declared dead.

Organ procurement starts in the intensive care unit of a hospital with a referral, which consists of a call from the ICU medical staff informing an organ procurement agency that a potential organ donor is undergoing treatment. This call is usually from an ICU nurse and often has been instigated by the nurse, but it always

requires the permission of the physician. At this point, the suitability of the donor is assessed by determining whether he is of an acceptable age, whether he has any disqualifying medical conditions, and whether his relevant organs are functioning properly. Each major organ has somewhat different criteria for suitability (Morris 1984; Cooper and Langa 1984; Calne 1983; Simmons 1984) and, indeed, each organ procurement program may have different criteria for organ use (UNOS 1987). The requirements for kidney donors are less stringent than the requirements for donors of other organs and, in practice, a multiorgan donor is one who has provided kidneys and one or more other organs. With the occasional exception of pediatric liver donors, all organ donors are kidney donors first. If the donor is acceptable, certain preliminary blood tests may be done before death is declared.

Once the OPA has received a referral and the technical evaluations have been completed, the family of the potential donor becomes the key decisionmaker. The Uniform Anatomical Gift Act allows a person to decide, prior to death, whether he wishes to be an organ donor in the event of his death (King and Grady 1985), but only about 17 percent of the public has signed a Uniform Anatomical Gift Act document (Gallup Organization 1985), which is provided on or with the driver's license in most states. In any case, no OPA will procure an organ based solely on such a document; it is the practice to ask the next of kin for permission to excise organs. This step in the process is emotionally difficult for all involved, but it is rarely unsuccessful. About 70–75 percent of families approached for permission grant it (Prottas 1985b).

Once permission is granted, a number of technical steps remain to be done. Arrangement must be made for the surgical teams, operating room time must be obtained, and the tissue-typing and cross-matching process must be readied. Once the organ has been excised, the final step of organ placement begins, and a suitable recipient is sought to receive the organ as a transplant.

Penetrating the market

Of all the steps in the organ procurement process, obtaining hospital referrals is the most problematic. Placing the organs, although controversial in some ways, is usually not difficult because demand for transplants chronically exceeds supply (National Task Force 1986). Obtaining surgical teams and the technical experts needed for immunological testing presents no significant problem; transplant surgeons need the organs for their own purposes, and the technical experts are paid for their work. The benefits to donor families are of a moral, not a material, nature, but obtaining their permission does not represent a serious bottleneck in the procurement process. Families are so likely to donate that referral rates, not permission rates, constrain the supply of organs (Prottas 1985b). In contrast, referrals must originate with doctors and nurses who get no direct benefit from the process and whose primary responsibilities are elsewhere. Getting the ICU staff to make a

referral is difficult for several reasons: it requires the staff's proactive behavior; it necessitates the staff's recognition of the failure of their primary lifesaving tasks; and it complicates and prolongs their interaction with the family of a patient they have failed to save (Prottas 1988). An OPA usually spends more time attempting to obtain cooperation from medical professionals than it does actually procuring organs (Prottas 1987c). Because ICU staff have other, more imperative demands on their time and attention, organ procurement agencies must increase the salience of organ procurement for ICU staff and the probability of their making the critical referral. Activities aimed at gaining medical cooperation are called "professional education." In fact, the educational content of professional education is small; motivation rather than information sharing is the primary goal. The information conveyed (for example, how to contact the OPA) is product-specific; the medical information is already widely understood (Prottas 1988).

But professional education is not the beginning of the organ procurement process, just as face-to-face sales are rarely the beginning of a marketing program. The initial step is selecting the hospitals with which an OPA will work. There are over 6,000 acute-care hospitals in the United States and the average OPA has at least formal relationships with about 50—too many for most OPAs to serve effectively (Prottas et al. 1987b). Some hospitals are far better sources of donors than others: hospitals with active trauma centers and neurophysicians are clearly better sources than small hospitals without these specialized resources, since organ donors are often trauma victims who would ordinarily be brought to a trauma center. The presence of a neurophysician is important because all organ donors must be declared brain dead, which usually requires the expertise of this type of physician. An OPA that concentrates professional education efforts on hospitals that are potentially better sources of donors is more likely to be successful.

Success at organ procurement also requires that the OPA orient itself away from the consumers of its product (the transplant hospitals and surgeons) and toward those who control the supply of organs (the community hospitals). In organ procurement, demand is never a problem; only supply is at issue. Consequently, the OPA must shift from a medical model—or even from a model as a medical supply unit to a transplant team—to a marketing model. An OPA must persuade doctors and nurses that cooperation in organ procurement is their professional and personal duty, without providing them any material incentives for their assistance. In effect, marketing altruism is the central task of organ procurement.

Recent growth in the organ procurement system

The United States has a large system for marketing altruism. Its organ procurement system is the largest in the world, dwarfing the next largest, the Eurotransplant Foundation, which serves Germany, Austria, and the Benelux nations (Cohen 1983, 1987). In 1986, the last year for which there are reasonably accurate data on procurement activity, there were about 100 OPAs operating in the United

Table 1. Growth in the United States Organ Procurement System, 1982–1986

	1982	1986
Active OPAs	82	100
Population served (in millions)	220	223
Hospitals served	2,500	4,450
Kidneys procured	5,070	7,750
Referrals received[a]	5,970	11,300
Waiting list (for kidneys)	6,000	11,500

a. Refers to all calls received from hospitals regarding potential cadaveric donors.

States (Prottas et al. 1987b). These organizations served virtually every part of the United States, had arrangements with almost 4,500 community hospitals, and procured some 12,000 organs—primarily kidneys,but also a substantial number of hearts and livers and limited numbers of pancreata and heart/lung combinations (Public Health Service 1987). In 1985, the organ procurement system spent about $240 million in direct procurement costs and $40 million in histocompatibility testing costs, in addition to the costs associated with the transplantations themselves (Kusserow 1987). As indicated in Table 1, the United States system grew substantially from 1982 to 1986.

The information on the organ procurement system reported in Table 1 was gathered primarily from surveys of OPAs performed by the author and colleagues at the Heller School, Brandeis University, in 1982 and replicated (with the addition of certain questions) in 1986. The response rate was 71 percent in 1982 and 86 percent in 1986. The national data reported are an extrapolation of these survey data, bolstered by data from the Health Care Financing Administration, to which all OPAs report their activities and finances. The potential errors that result from this extrapolation in 1986 are very small because actual data were available for most variables for over 90 percent of OPAs. The 1982 errors could be larger because coverage was less complete. In addition, the average nonresponding OPA in 1982 was smaller than the average respondent and so, in general, the 1982 estimates are somewhat exaggerated, which minimizes the amount of change between 1982 and 1986 (Prottas 1985b; Prottas et al. 1987b).

Not only has the overall system grown since 1982, but there have also been substantial changes in the operations of individual OPAs. Since 1982, the average OPA has grown by almost every measure (see Table 2). The only aspect in which the average OPA has decreased in size is in its catchment area ("population served" in Table 2). By 1982, virtually the entire U.S. population was being served by an OPA, so the increased number of OPAs inevitably meant a decrease in their average catchment area. Indeed, the rate of increase in the number of OPAs during these years is unprecedented and may be the result of several convergent forces. The number of transplant centers has increased rapidly, especially the number of nonrenal centers (Public Health Service 1987), and medical politics often makes cooperation among transplant hospitals more difficult than the development of a com-

Table 2. Growth in the Typical OPA, 1982–1986

	1982	1986
Population served (in millions)	3.35	2.60
Hospitals served	36.5	48.8
Hospitals supplying donors	13.4	15.5
Kidneys procured	51.0	87.8
Number of referrals	85.3	124.3
Waiting list	85.4	131.8

Source: Prottas 1985b; Prottas et al. 1987b.

peting OPA. In addition, the federal intention to begin the regulation of OPA service areas was widely anticipated during this period, and many OPAs may have been founded to position themselves against such regulation.

More recently, there have been efforts to consolidate OPAs that operate in a single city or state, both to deal with federal requirements and in recognition of the increased effectiveness of larger consolidated systems. In 1988, the number of OPAs decreased for the first time. Under federal pressure, a number of agencies consolidated, and only 71 were officially certified by May 1988. Several additional agencies will probably be added soon (Modern Healthcare 1988). Consolidation has decreased the number of OPAs and thus increased catchment areas again. However, some consolidations may be more pro forma than real.

There have been other organizational changes in the system. In particular, many OPAs have been restructured as freestanding entities. Since organ procurement agencies began to operate on a large scale about fifteen years ago, there have been two distinct organizational forms—hospital-based OPAs (HOPAs) and independent OPAs (IOPAs). For most of the history of organ procurement, HOPAs have predominated; as late as 1982, two-thirds of OPAs were hospital-based (Prottas 1985b). HOPAs are usually located in the department of surgery or the division of transplantation. These agencies are generally under the direct supervision of a transplant surgeon and are often staffed by nurses previously employed in the hospital's transplant service, dialysis service, or intensive care unit. In general, HOPAs serve only the transplant hospital in which they are located.

IOPAs are separately incorporated entities that provide only organ procurement services and that usually serve several transplant hospitals. Their direction comes from a board representing the transplant units of the affiliated hospitals. IOPAs have been larger than HOPAs, have had more full-time as opposed to part-time employees, and have been the more effective segment of the organ procurement system. In 1982, IOPAs procured 55 percent of the nation's donated organs while representing only 33 percent of the nation's OPAs (Prottas 1985b). Since 1982, the number of IOPAs has grown at the expense of HOPAs; in 1987, there were more IOPAs in the country than HOPAs (Commerce Clearing House 1988b).

There are several reasons for the shift to IOPAs. First, IOPAs have been more effective at obtaining organs. As the demand for organs has increased and as the

procurement system has become more sophisticated, the advantages of organizational independence have become clearer. In addition, federal regulations requiring that there be only one OPA in a metropolitan area have forced a number of HOPAs to reconfigure (Commerce Clearing House 1988a). Finally, some HOPAs have reorganized as IOPAs simply to escape the personnel system of hospitals, a change that reflects the uniqueness of the organ procurement function. The organizational and structural changes in the organ procurement system have contributed to equally striking changes in the ability of the system to locate and obtain donors.

The effectiveness of organ procurement

There are several ways of measuring the effectiveness of organ procurement programs. The "bottom line" of organ procurement is the number of organs actually procured. Ideally, this number would be presented as a percentage of the potential supply of organs. There have been numerous attempts to calculate the total number of potentially suitable organ donors who die each year in the United States, and none is completely satisfactory. The more persuasive estimates range from 17,000 to 26,000 potential donors each year (Maximus 1985), but the quality of these estimates is questionable and none is sufficiently trustworthy to apply to an area as small as the service area of the average OPA.

The standard approach for certification purposes (Commerce Clearing House 1988a) has simply been to measure kidneys procured on a per capita basis—that is, kidneys procured divided by the population served by the procurement agency. Kidney procurement is the standard measure for two reasons: first, the fact that virtually all donors donate kidneys makes possible a highly accurate count of donors; second, the demand for kidneys is permanent and assumable—rarely is a donor rejected because there is no recipient for the kidney. In contrast, the number of nonrenal organs procured can be affected by the availability of recipients of certain types and by geographic factors. It is not uncommon for a heart donor to be refused because no suitable recipient can be found or because timely transport of the organ to a recipient is impossible. Nonrenal organs have very short preservation times (Evans 1985). (Donor counts are somewhat preferable to kidney counts, but reporting practices provide the latter, not the former.)

Another helpful evaluative figure is the number of nonrenal donations. The growth of nonrenal transplantation has made the percentage of donors who are multiorgan donors a matter of considerable importance. However, while large differences in the number of multiorgan donors among programs might indicate different levels of effectiveness, this number is not wholly within the control of an OPA because nonrenal organ demand can affect the procurement of these organs. In contrast, the kidney discard rate is widely used as an evaluative measure because the discard rate of kidneys is largely within OPA control. A kidney procured but not transplanted has no social (or, for that matter, economic) utility.

There are also two intermediate, process measures that are of interest. Because referrals are a key step in the organ procurement process, referrals per capita pro-

Table 3. Growth in the Effectiveness of the OPA System, 1982–1986

	1982	1986
Kidneys per million population	20.3	33.5
Kidney discard rate (%)	18.7	12.5
% of multiorgan donors	—	56.0
Referrals per million population	29.3	41.3
% of referrals that become donors	40.1	36.1
% of families granting permission	71.5	71.4

Source: Prottas 1985a; Prottas et al. 1987b (reproduced from Prottas 1985a, 1987c).

vide helpful information regarding the success of an agency's critical marketing effort. Permission from donor families is also a necessary condition for a procurement; thus permission rates have importance as well.

Table 3 displays the striking improvement in the organ procurement system in recent years. In 1982, the U.S. already had the most effective organ procurement system in the world, procuring many more kidneys on a per capita basis than its nearest competitor, Eurotransplant (Prottas 1985a). Its lead has subsequently increased (Cohen 1987). The fact that the average OPA in 1986 was as effective as the most effective 10 percent of OPAs in 1982 provides clear evidence of improvement.

There are no comparative data regarding multiorgan procurement, but the percentage of donors donating nonrenal organs has certainly grown. There has been great pressure on the organ procurement system because of the technical and logistical demands of nonrenal procurements, but the system has responded with extraordinary speed and success.

Even kidney discard rates, a nemesis of American organ procurement, have improved. The Eurotransplant Foundation routinely reports discard rates of 4–6 percent (Cohen 1983, 1987), but American rates have consistently been of another order of magnitude, ranging from 12 to 20 percent. Although American discard rates remain very high by international standards, they have dropped in recent years (Lucas 1987).

The process measures have also improved. Referrals have risen substantially, even more so than donations. The resulting decrease in the percentage of referrals that lead to donation is also good news. High ratios of donations to referrals result from the preselection of donors by ICU staff. Traditionally, medical professionals decided which families to ask to donate organs, based on their social and psychological evaluation of the family. ICU staffs are not very good at such evaluations, and the results were generally high permission rates, high donor/referral ratios, and low numbers of organs. The data in Table 3 indicate that OPAs are overcoming this preselection tendency, with beneficial effects on organ supply. Permission rates remained more or less constant over this period, and are generally quite high. The improvements in the organ procurement system reflect important changes in the structure of the system and its development into a more homogeneous and mature industry.

Explaining success: Changes and growth

The assertion that success in organ procurement is primarily dependent on successfully motivating the cooperation of the medical staff of ICUs is not based wholly on an abstract analysis of the production function of organ procurement. The survey data were analyzed using standard regression techniques (see Table 4).

Several points can be made from these data. In 1982, IOPAs were significantly more effective than HOPAs. Because IOPAs were also significantly larger than HOPAs, size per se had no effect across the entire sample of OPAs. (Size was measured in terms of OPA activity rather than service area.) However, size did matter when HOPAs were analyzed separately (results not shown). The operational approach of IOPAs—distance from the transplant team, more full-time professional staff, the existence of nonmedical administration, and orientation toward community hospitals—contributed to the difference in effectiveness.

The central importance of professional education and referrals is seen in the positive coefficient for referrals per capita. The negative coefficient for the permission rate in 1982 can be explained by the preselection issue discussed earlier. Other factors were so important in organ procurement that the rate at which permission was obtained from families had no effect on the supply of organs. In essence, these data indicated a system of uneven capacity in which structural variables, acting as surrogates for a number of operational factors, accounted for much of the great variation found in success rates across OPAs.

The same analysis applied to the 1986 data shows some striking changes in the organ procurement system. The importance of medical cooperation remained—indeed, it increased. Organizational structure had a much smaller effect, while organizational size became important. The estimated effect of the permission rate became positive, in contrast to the negative effect this variable had in 1982.

What has occurred is a convergence and maturation of the organ procurement system, resulting in increased effectiveness. The effect of "group" in 1982 was anomalous in that it reflected no concrete activity leading to success, but was a surrogate for a constellation of approaches and strategies. The IOPA/HOPA differential reflected a failure on the part of a substantial portion of the organ procurement industry to understand the production function of its own product. HOPAs were so psychologically tied to their relationship to the transplant service that they could not address the key activities of organ procurement. By 1982, most IOPAs had come to see themselves as agencies marketing a service to community hospitals (the suppliers of donors), while HOPAs continued to see transplant hospitals as their primary clients. This basic misunderstanding created incongruence between their task environment and the way they organized their work. The elimination of the differences between HOPAs and IOPAs by 1986 reflects the successful diffusion of the marketing model throughout the organ procurement system. It was easier for OPAs outside transplant hospitals to make that shift, but,

Table 4. Regressions on Kidneys per Capita Data

Explanatory Variables	1982 Standardized Coefficient	1982 Unstandardized Coefficient	1982 *t* ratio	1986 Standardized Coefficient	1986 Unstandardized Coefficient	1986 *t* ratio
% of families granting permission	−0.25	−1.81	−1.59	0.26	0.23	2.94*
Group HOPA = 1 IOPA = 0	−0.37	−6.75	2.17**	−0.11	−3.64	−1.28
Referrals per capita	0.27	0.13	1.79***	0.48	0.13	5.36*
Size	0.062	0.011	0.38	0.26	2.89	2.82*
Constant	—	40.13	3.05*	—	6.68	0.85
		$R^2 = 0.31$			$R^2 = 0.40$	
		$\bar{R}^2 = 0.25$			$\bar{R}^2 = 0.37$	
		$F(4,42) = 4.73$			$F(4,78) = 12.92$	

*Statistically significant at the 1% level (two-tail test)
**Statistically significant at the 5% level (two-tail test).
***Statistically significant at the 10% level (two-tail test).
Source: Unpublished data from surveys conducted by the author and colleagues, Heller School, Brandeis University.

as the 1986 data show, OPAs that are still located within transplant services have been able to make the shift as well.

The increased nationalization and professionalization of organ procurement may partially account for this improvement. During the last five years the professional association of transplant coordinators has grown, and there is now some mobility of experienced coordinators between OPAs, a phenomenon that was unheard of five years ago. Other organizations—the Association of Independent Organ Procurement Agencies, the United Network for Organ Sharing, the Association of Transplant Surgeons, the Association of Transplant Physicians, the American Council on Transplantation, and others—have also appeared and taken more aggressive and visible roles. Governmental activity has also increased, as reflected in the passage of the National Organ Procurement Act and in the formation of the National Task Force on Transplantation and of the Division of Transplantation in the Public Health Service. Some of these activities and agencies have served as conduits for knowledge, as have the scores of conferences, meetings, and workshops each year; in other cases, the mere existence of activity at the national level has raised the OPAs' consciousness of their place in a national community. The changed environment has served to reorient OPAs from seeing themselves as *sui generis* in a local medical community to having relationships and analogues across the nation—clearly a better environment for learning.

The homogenization of OPAs has made the operational mastery of their core technology more important in explaining success. The explanatory power of "referral" is the finding most consistent over the two studies, being positive and significant both times. The power of this variable was greater in 1986 because most OPAs are now engaged in the right tasks, so how well they do them matters more.

The most striking change from 1982 to 1986 is the reversal of the sign of the family permission variable. In 1982, we actually found a negative relationship between permission rates and organ procurement. This paradoxical finding reflected the extremely poor job done by some OPAs in generating referrals. If the only families approached are those whose receptiveness is glaring, one gets many permissions and few organs. Since 1982, the organ procurement system has improved to the point that the "natural" relationship between permission rates and organ procurement has appeared, which indicates a far higher level of competence on the part of the average OPA.

The 1982 findings in Table 4 show that size had only a small independent significance in the regression but did have a strong Pearson correlation coefficient. In effect, the influence of size was subsumed under that of "group." As the difference between IOPAs and HOPAs disappeared, the effect of the size of the OPA clearly appeared in the 1986 data. There are certain advantages to larger scale in organ procurement, especially in marketing to medical professionals. Larger OPAs can make better hospital selections; some hospitals are better sources of referrals than others, and larger OPAs have a larger hospital pool from which to select. Furthermore, their larger staffs enable them to maintain systematic programs of professional education in the face of the short-term imperatives of organ donation.

OPAs operate in two very different time/intensity environments. An actual organ procurement is unpredictable and time-sensitive and must take absolute priority over all other activities. However, a predictable and systematic program of marketing to medical professionals is the key to the long-term success of the agency. A smaller agency often has difficulty in protecting its long-term marketing efforts from the immediate necessities of organ donation. In addition, larger agencies can provide better service to community hospitals. Organ procurement is a 24-hours-a-day, seven-days-a-week business, and quick response to a referral is a necessity at all times. Coverage is far easier for an OPA that is staffed for 150 donations a year than it is for one staffed for only 20.

Unlike "group", "size" is a variable that has a direct relationship to the operational character of organ procurement. Its emergence as an explanatory factor, like the role of referrals and permission rates, reflects the maturation of the organ procurement industry. In 1986, most OPAs were engaged in activities that are central to success; differences among OPAs increasingly became a function of how well they did their jobs rather than whether they performed those jobs at all.

Conclusion

Only in the last four or five years have OPAs been willing to consider organ procurement a business. The antecedents of individual OPAs operated against such a perception. In 1980, OPAs were small, were under the direction of transplant services, and had been formed to supply transplant services with their raw materials. They were staffed by nurses working for doctors and understood their responsibility to be to the users of organs—ultimately patients, but proximally surgeons. OPAs that moved away from this model sought to serve families rather than community hospitals; they viewed themselves as social service organizations whose primary responsibility was to help families deal with loss. The strong support of many OPAs for public education efforts reflects their continued commitment to the mission of serving families. However, neither of these self-definitions—directing services to transplant surgeons or to donor families—is very constructive. The former directs efforts into useless avenues, while the latter concentrates attention on a nonexistent (or at least secondary) problem.

Only slowly did OPAs begin to understand the real nature of the procurement industry. Their job was to procure organs, and the ICUs of community hospitals controlled their access to donors. The people they had to motivate and serve were not transplant surgeons, but neurophysicians and intensive care nurses. The location of their clientele was not the tertiary transplant hospitals, but the trauma centers and the active suburban hospitals. OPAs had to sell something to ICU doctors and nurses: a chance to do good, to salvage something from the medical professionals' failure to salvage life. Concretely, they were performing a service: donor evaluation, donor maintenance, family relationship management, and organ procurement and use. On the one hand, they had to offer the doctor and nurse a

reason to want these services; on the other, they had to provide the services with sufficient speed and skill so that no professionals would regret having made a referral.

By 1982, it was clear that some OPAs were beginning to absorb these lessons and work out operational routines to apply them. It was also clear that many (mostly HOPAs) had not yet learned what they were all about. Four years later, much had changed. The industry had grown, its national self-awareness had burgeoned, and mastery of the core technology had spread remarkably. Whether the demand for nonrenal organs could have been met prior to this maturation is unknown; perhaps the intense pressure to obtain hearts and livers spread the diffusion process. In any case, with improvement in donor location came improvement in procuring more organs from those donors found. By 1986, differences in the execution of key activities began to influence the bottom line—surely the sign of a more developed industry.

The next stage of development may lie in the explicit application of business practices to OPA operations. Few OPAs are yet capable of systematically analyzing and planning marketing strategies, utilizing information technologies, or managing sales forces. Many OPAs still lack the leadership, time, and skills to be concerned with improving the efficiency of their resource utilization. However, some are beginning to experiment with the application of modern management tools to organ procurement. If they are successful, we may soon see a second round of diffusion and outcome improvement.

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The Economics and Ethics of Markets for Human Organs

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Abstract. In 1984, federal legislation outlawing payment for human organs for transplantation was adopted after only cursory discussion of the underlying policy issues. More considered analysis suggests that this prohibition may be overly broad. It appears possible to design suitably regulated market-type approaches to the acquisition and allocation of cadaveric organs (and perhaps of organs from living donors as well) that will be neither unduly offensive to ethical sensibilities nor easily abused and that may yield significant improvements over the existing system of organ procurement, which presents important ethical and practical problems of its own. Moreover, whatever ultimate judgment we reach concerning the merits of markets for transplantable organs, analysis of the sources of the initial moral resistance to the commercialization that lies behind measures such as the 1984 legislation offers insights into the respective roles of market and nonmarket institutions in general.

Recent advances in the technology for transplanting human organs have led to a large increase in the demand for suitable organs. As a consequence, demand now considerably exceeds supply (U.S. DHHS 1986; Lee 1986). This situation gives rise to two policy problems: First, can we and should we increase the overall supply of organs? Second, how should we allocate the existing scarce supply among the many individuals who would benefit from a transplant? In the United States, markets are the conventional mechanisms used to deal with both of these issues for most goods and services. At present, however, federal law (as well as the laws of many states) prohibits the commercial sale of organs and thus rules out market solutions to problems of organ study and distribution.

In this essay I will analyze the advantages and disadvantages of markets for human organs, explore the ways in which such markets might be organized and regulated, and assess the wisdom of the statutes that outlaw such markets. The subject, which is complicated in any event, is rendered even more difficult because it is heavily fraught with strong moral sentiments. To many individuals, the notion of employing markets in such a setting is deeply disturbing. I will take these moral

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concerns seriously here. In particular, I will ask whether it is possible to design compensation schemes that are not strongly antithetical to our ethical intuitions. But beyond this, I will also explore why it is that these intuitions (at least initially) often run so strongly counter to the notion of paying compensation for transplantable organs.

Whatever our initial sentiments, we have an obligation as a society to inquire seriously into these difficult issues. Each year many thousands of lives are lost for lack of transplantable organs and hundreds of millions of dollars are spent on the existing transplant system[1]—and these figures are likely to increase significantly in the future. We cannot afford to reject any approach that would increase the supply of organs or improve the efficiency with which organs are allocated and transplanted without the most thoughtful consideration. Moreover, careful analysis of this subject promises to illuminate other areas where prohibition of commercial sales is currently a topic of serious debate, such as adoption[2] and surrogate motherhood.

The Current Legal Regime

Historically, the common law did not provide anyone with a clear property right in a human corpse, and thus did not give anyone the authority to transfer a cadaver or any of its parts for any purpose by gift or sale (Vestal et al. 1954).[3] Thus when transplants first became feasible, there was no legal mechanism whereby individuals could designate that their organs could be used for transplants upon death. To rectify this situation, the Uniform Anatomical Gift Act (UAGA) was promulgated in 1968 and adopted in some form in every state by 1973 (Michigan Law Review 1974). The UAGA explicitly gives individuals the right to designate prior to death whether their bodies or organs are to be donated for transplants. In cases where a decedent's wishes are not known, the act gives the next of kin the right to designate whether or not organs are to be donated.

The UAGA deals expressly only with donations of organs; it is silent on the subject of sales. According to the chairman of the committee that drafted the UAGA, it was intended neither to encourage nor to discourage remuneration: "... it is possible, of course, that abuses may occur if payment could customarily be demanded, but every payment is not necessarily unethical. ... Until the matter of payment becomes a problem of some dimensions, the matter should be left to the decency of intelligent human beings" (Stason 1968: 928).

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1. In 1985, the Medicare program paid $285 million for kidney transplants alone (Schuck 1989).
2. See Landes and Posner (1978), Prichard (1984), and Boston University Law Review (1987).
3. This does not mean that sales or gifts were illegal, but only that contracts for sale or deeds of gift were not enforceable at law.

In the 1960s (prior to the adoption of the UAGA) some states adopted statutes explicitly prohibiting the sale of human bodies and organs. Most of these states repealed such statutes when they adopted the UAGA.[4] It is unclear whether these repeals were simply the result of a program of repealing all relevant statutes predating the UAGA or whether they reflected a judgment that the prohibitions on sales were either overridden by the UAGA or, conversely, made redundant by it. In any event, Delaware evidently did not hold the latter view, since it added an explicit prohibition on sales to its version of the UAGA.[5]

The status of the sale of organs for transplantation therefore remained uncertain until Congress adopted the National Organ Transplant Act (NOTA) in 1984. NOTA was essentially an effort to enhance the system of voluntary provision of transplantable organs contemplated by the UAGA. Its principal provisions established federal financial support for local nonprofit organ procurement organizations and for a national organ procurement and transplantation network to assist in matching organ donors and recipients. However, NOTA also effectively outlawed commercial markets in transplantable organs by making it a federal crime "for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce."[6] Several states have subsequently supplemented this act with separate statutes of their own outlawing the sale or purchase of human organs.[7] As a consequence, any effort to establish a market for organs today would require the repeal or amendment of legislation at both the federal and state levels.

Neither the federal nor the state legislation outlawing markets for organs were accompanied by careful policy analysis justifying the ban. NOTA did, however, establish the federal Task Force on Organ Procurement and Transplantation to inquire further into the policy issues raised by transplants. But when the task force submitted its report in 1986 it reaffirmed NOTA's ban on the commercialization of organ transplantation without further analysis, simply offering the conclusory observation that "society's moral values militate against regarding the body as a commodity" and suggesting that such a ban is appropriate to "encourage altruism" (U.S. DHHS 1986: 96). The task force also proceeded to encourage individual states to adopt their own prohibitions on the commercial sale of organs because NOTA, limited as it is to sales affecting interstate commerce, might not be entirely effective in suppressing such sales.

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4. E.g., Law of Aug. 1, 1968, ch. 429, sec. 7, 56 Del. Laws 1773, 1773 (1967) (repealed 1970); Law of April 22, 1964, ch. 702, sec. 1, 1964 N.Y. Laws 1827, 1828 (repealed 1971); Act of June 12, 1967, ch. 353, 1967 Mass. Acts 202, 202 (repealed 1971).

5. Del. Code Ann. tit. 24 § 1783(f) (1981).

6. 42 U.S.C. § 274(e) (1982). The act specifies that its prohibition does not extend to payments made to cover costs incurred in the process of transplanting the organ.

7. These states include Virginia, Maryland, and California. For a partial survey see Virginia Law Review (1985).

In the discussion that follows I will seek to offer a more comprehensive analysis of NOTA's proscription of commercial sales. For this purpose it will be helpful to distinguish between the use of markets to encourage individuals to make their organs available for transplantation and the use of markets to allocate the available supply of organs among the individuals who wish to receive them. As Calabresi and Bobbitt (1978) have emphasized, in "tragic" contexts (such as life-saving organ transplants) it is entirely possible and often quite appropriate to use a market for one of these purposes and not the other. Consequently, I will consider these two different uses for markets in turn.

Markets for Procuring Organs

Some organs can be obtained from living donors. This is true of kidneys in particular, since most individuals can lose one of their two kidneys without serious impairment of their health. It appears that in banning commercial sales of organs, the authors of NOTA and of the similar state statutes were focusing particularly on sales by living donors, and especially on one notorious effort by a former Virginia doctor, whose license had previously been revoked for fraud, to establish a company to solicit living individuals (including indigents from the third world) to sell one of their kidneys for transplantation in transactions to be brokered by the company for a profit (Virginia Law Review 1985: 1020–22). Most transplantable organs, however, are "harvested" from cadavers, and indeed many organs, including livers, hearts, and lungs, can only be obtained from persons who are deceased. I will therefore focus first on markets for cadaveric organs, then turn to the issues raised by sales of organs from living donors.

Markets for cadaveric organs

Current estimates indicate that of the roughly 20,000 Americans who die annually under circumstances that would make their organs suitable for harvesting, only about 15 percent actually donate their organs.[8] One important reason for this low donation rate is that relatively few individuals fill out and carry organ donor cards or otherwise indicate their willingness to donate their organs prior to death.[9] And although under the UAGA the deceased's next of kin can authorize donation, attending physicians are understandably reluctant to press for such permission[10] and families are often reluctant to give it, particularly under the difficult circum-

8. S. Rep. No. 769, 98th Cong., 2d Sess. 4 (1984); U.S. DHHS (1986: 35).

9. Polls indicate that only 17 percent of Americans have actually completed donor cards (Gallup Organization 1985). Presumably fewer actually carry such cards.

10. The primary obligation of the attending physician is, of course, to the patient and the patient's family, not to the potential recipient of the patient's organs.

stances surrounding death.[11] However, these low authorization rates evidently do not reflect widespread opposition to the idea of donating organs. Surveys indicate that more than 70 percent of Americans support the concept and express a general willingness to donate (Koop 1984).

These observations suggest that with some effort, donation rates might be increased substantially. Current policy proposals focus principally on three different types of measures that might be adopted for this purpose: (1) "required request," under which health care professionals would be required by law to ask the family of a deceased or dying person to donate the deceased's organs (U.S. DHHS 1986); (2) "presumed consent," under which organs would be assumed available for transplantation unless an objection had previously been registered, either by the decedent prior to death or by the next of kin at the time of death (Dukeminier and Sanders 1968); and (3) "mandated choice," under which all individuals over a certain age would be required by law to choose at some point—perhaps upon applying for a driver's license or for a social security card—whether or not to make their organs available for transplants upon their death (Katz 1984). There is reason to believe, however, that the first two of these policies do not promise a substantial increase in donation rates: required request statutes have already been adopted in at least 28 states, with only limited results (Gerson 1987),[12] while presumed consent laws are in force in fourteen European countries, none of which have notably better donation rates than the United States.[13] And the mandated choice approach, although holding some promise of a further increase in donation rates, has the disadvantage that in itself it provides no special incentives for people to choose in favor of donation.[14] It is worth inquiring, therefore, whether offering compensation might lead to substantially higher donation rates without excessive offsetting disadvantages.

Feasible designs for a market. Before we can evaluate the desirability of having a market for organs, it is important that we have clearly in mind the particular forms that the market might take.

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11. Moreover, even when the deceased has indicated an intention to donate, hospitals are generally unwilling to proceed unless the family also expresses agreement. (Interview with Frances Angeletti, transplant organ procurement coordinator, Department of Surgery, Yale–New Haven Hospital, 10 December 1987.)

12. A variant of the required request approach has now been imposed on all hospitals receiving funds under either Medicare or Medicaid by the Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 1138, 100 Stat. 4599 (1986).

13. In practice, evidently even strict presumed consent laws are functionally equivalent to the prevailing American approach under which the approval of the next of kin is required (Gerson 1987).

14. The mandated choice approach also runs a risk similar to that presented by the insurance premium deduction scheme discussed below. If a substantial number of individuals were to choose not to donate, then presumably this choice would have to be respected upon their death, thus foreclosing the possibility of persuading their next of kin to donate their organs on their behalf. It is therefore possible that the mandated choice approach, absent any inducements to make the choice in favor of donation, could lead to a reduction in the overall rate of donation.

Purchasing organs from dead people is obviously impossible. It also seems unwise to seek to purchase the rights to a person's organs while they are awaiting death: such transactions would often be traumatic for all concerned, and patients might be worried that if they agreed to sell, the care they received subsequently would be less than zealous. Moreover, since a large fraction of potentially harvestable organs come from people who die suddenly in accidents, such transactions would often be infeasible in any event. Seeking to purchase the right to remove a decedent's organs from the next of kin at the time of death is also a dubious policy: there is little time to arrange the transactions, and the transactions would be extremely awkward and often traumatic for the family members involved, who would have to decide under difficult emotional circumstances whether to accept a (potentially quite large) sum of money in return for something they (and others) might well feel is not theirs to sell. (This is not to say that serious proposals for such compensation have not been suggested. For example, it has been seriously proposed, even by individuals who express strong opposition in the abstract to the idea of compensating organ donors, that organ procurement agencies offer to pay funeral expenses for poor families if they will agree to donate the organs of a deceased relative. It has been suggested that this might be particularly helpful in encouraging donations among minorities, who evidently are often especially reluctant to donate because, among other things, they are suspicious that their deceased relative's organs will simply be used to help prosperous white people. Such a policy, which would clearly violate NOTA, is of course subject to the serious objection that it appears to patronize and exploit the groups to whom it is targeted.)

It therefore appears that the most feasible method for establishing a market in cadaveric organs would be to structure it as a futures market—that is, the right to harvest a person's organs upon death must be purchased from him while he is alive and well. (Although the term *futures market* may bring to mind misleadingly offensive images of hog bellies and the Chicago Commodities Exchange, I will nevertheless use the expression here for economy of reference. As I will try to make clear, a futures market for cadaver organs need look very little like the market for spring wheat.)

The most explicit proposal to date for such a futures market has been made by Schwindt and Vining (1986).[15] They describe a system under which an individual would receive a current cash payment in exchange for the right to harvest their organs if they should die under circumstances in which their organs were transplantable. Schwindt and Vining seem to envisage that the resulting contract would be binding for the rest of the donor's life. They further propose that the government be made the sole purchaser of such rights. Upon examination, however, neither of these central features of their proposal seems necessary or desirable. There is no need for an individual to enter into a futures contract of lifetime duration; in

15. For another, much less detailed proposal, see Brams (1977).

fact, annual contracts appear both feasible and preferable. Further, there is no need to make the government the sole purchaser. Schwindt and Vining support this latter aspect of their plan with the argument that the economies promised by a central clearing mechanism for matching donors and recipients make the organ procurement system a natural monopsony. Yet it is possible to have a centralized clearing system while still having multiple purchasers and holders of property rights in organs.

These points become clearer if we consider alternative approaches. One of the most promising alternatives is to make providers of health insurance the principal purchasers of future rights in organs. I will describe and analyze a scheme of this type in some detail here. There are also a number of other ways to purchase future rights in organs. For example, a bill was recently introduced in the Connecticut legislature calling for a refund of $10 of the fee for the renewal of a driver's license for individuals who agree to donate their organs.[16] Each such scheme has its particular advantages and disadvantages—and all are currently proscribed by NOTA. I will concentrate on the health insurance approach here, however, in order to provide a clear focus for my discussion.

A health insurance premium reduction plan. Health insurance companies would be natural purchasers of future rights to organs because these companies are already involved in the types of actuarial calculations and financial transactions that would be involved. Insurers might simply insert in their annual premium statements a provision (a check-off box would probably suffice) by means of which their policyholders could indicate that, in case they were to die during the period (generally the coming year) covered by the premium statement, the insurance company or its assignees would have the right to harvest any of the insured's organs that were transplantable. In return for checking this box, the insured would receive a specified reduction in their insurance premium for that period. Individuals would be free to change their mind about being a donor annually (or whenever their insurance policy was renewed).[17]

Each insurance company would submit to a central national registry the identification of each of its insureds who had chosen the donation option. Hospitals would then be required to check this national registry upon the death of any patient whose organs are potentially suitable for transplantation.[18] If the patient were enrolled in the registry for the current year, the hospital would indicate which of the

16. Proposed bill no. 5456, Connecticut General Assembly, February session (1988).

17. In order to have the forces of inertia work in favor of organ donation (and also to avoid making insureds repeatedly confront a difficult issue), policy renewals could be structured to provide that once an individual had elected to donate in return for a premium reduction, that option would be automatically renewed unless the insured took some affirmative action to revoke it.

18. Hospitals might be required by governmental regulation to check the registry, or induced to do so either by offer of a payment for each registered transplantable organ they locate and/or by liability for failure to check the registry to determine the owner, if any, of the rights to the organs.

patient's organs were available, and suitable recipients could be located through the national matching network. A recipient of one of the deceased's organs (or the recipient's health insurer) would then be obliged to pay the deceased's insurance company, or their assignee, the latter's stated price for an organ upon accepting it for transplant.

Group health insurance policies, which cover a substantial fraction of the nation's workforce, might deal with the problem of individual choice in several ways. One approach would be to provide that all workers under a given employer's plan will be presumed to agree to donate unless they complete a form indicating otherwise, in which case an additional payroll deduction would be made for their health insurance coverage. Such an approach—especially if combined with a promotional program sponsored by the employer, the union, and the local public health department stressing the social value of donation—might well assure very high levels of donation.

All types of health insurance companies—for-profit, nonprofit (Blue Cross/Blue Shield), and even governmental (Medicare/Medicaid)—could participate in such a scheme. The insurance companies would act primarily as intermediaries, purchasing and then reselling rights to harvest organs. Many insurance companies might choose to resell their futures contracts to other firms that would specialize in holding such contracts.

Institutions or individuals other than health insurance companies might also be permitted to solicit organ futures. One advantage of thus broadening the range of purchasers and holders of rights is that it might help bring within the system the roughly 13 percent of the population that is not currently covered by any form of private or public health insurance (U.S. Department of Commerce 1987).[19] On the other hand, a disadvantage is that it would be more difficult to assure that all futures are purchased honestly and recorded accurately. Moreover, there might be a tendency for some firms to seek out and solicit organ futures from individuals who are unusually promising as prospective donors. For example, companies selling motorcycle insurance might find it attractive to offer very large cash payments or premium reductions for organ futures to motorcyclists, whose death rate is high and whose organs have a good probability of being harvestable in case of death since they are generally young and often die of head injuries.[20] Or, if there were

19. Donation decisions for minor children would presumably be made on their behalf by their parents, since children are commonly covered by the same health insurance policy that covers the rest of the family.

20. The chance that the average motorcyclist will die in a vehicle accident during a given year is presently on the order of 1 in 1,000 (Insurance Institute for Highway Safety 1987). If all of the organs recoverable from a cadaver were on average worth $100,000 collectively, and if organs could be recovered from one-third of all the persons killed in motorcycle accidents, then a futures contract for the average motorcyclist would be worth roughly $33 (and more if the risk of death from other causes were factored in as well). If the total value of the organs harvestable from a single individual were $1,000,000, then the futures contracts would be worth at least $333.

no limitations whatsoever on the solicitation of organ futures, some private firms or individuals might find it attractive to seek out, say, particularly rowdy motorcycle gangs and buy up organ futures from their members for cash. While such targeted solicitation activity would not necessarily be undesirable, it might give rise to at least two types of costs. First, the solicitation activity itself, if carried to an extreme, might appear distastefully sanguinary to a substantial segment of the public. Second, free entry could lead to a wasteful duplication of solicitation efforts. If these problems were to appear sufficiently serious, they would provide a further argument for limiting the right to solicit organ futures to general health insurers, which would probably offer premium reductions for organ futures based only on a few general factors, such as the insured's age.

With a futures market, any individual who had not sold a futures contract for their organs would presumably be deemed not to wish to have their organs made available for transplant. Thus the system need not be accompanied by a right to seek to purchase an individual's organs after he had died, whether from his estate or from his next of kin. Rather, a decedent's organs could be made purchasable only from a firm holding a valid futures contract that was executed by the deceased prior to his death. (It would be possible to permit an individual who had not signed a futures contract to designate in his will that his estate or next of kin would have the right to sell his organs upon his demise if the organs were harvestable. That is, his estate or next of kin would hold the future. But it might be appropriate to disallow this option: most individuals, being risk-averse, would presumably find it less attractive than selling a future while living, and permitting it might provide an added inducement to suicide for some individuals.)[21]

Determining prices. The price (premium reduction) that insurance companies would pay for the future right to cadaveric organs would depend on the price that they could obtain for those organs at the time of removal. Since the health insurance business is reasonably competitive, presumably insurance companies would be able to take only a market rate of return for their efforts as intermediaries in such transactions; the rest of the (expected) price received by the insurance companies for the harvested organs would be passed through to their insureds in the premium reductions offered them.

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21. If, upon an individual's death, the family objected to donation even though the individual had sold the rights to his organs, there would be an awkward problem. There are at least three possible responses: ignore the protest; permit the family to prevent the donation, but only upon paying the market value of the harvested organs; or respect the family's wishes (at least if they appear to feel very strongly on the matter) without requiring payment from them beyond refund, with interest, of the insurance premium reductions the family had received in the past. Although the first and second are the only responses that respect the transaction for sale of the organ futures, there might be considerable pressure to accept the third. Fortunately, anecdotal evidence suggests that it is almost unheard of for families to refuse consent when the deceased has clearly indicated a desire to donate their organs, so this should not be a common problem.

How would the price for the harvested organs be determined? One possibility would be simply to establish a market in harvested organs, and to let the forces of supply and demand determine the ultimate price. This possibility is explored more carefully later in this article. The system would also be perfectly workable, however, if the price that an insurance company could obtain for a cadaveric organ were set administratively by the government rather than by market forces. For example, the government could simply provide that an insurance company (or its assignee) is entitled to receive no more than, say, $10,000 for a kidney, $20,000 for a heart, $15,000 for a liver, and so forth. The insurance company would then set its offered premium reductions on the basis of these prices, discounted by the probability that the insured will die during the coming year and the probability that the insured's organs will be usable in case of death.

In particular, such a scheme could be employed in the context of the existing system for organ procurement. Under that system, organs are harvested and distributed through a network of roughly 70 regional organ procurement agencies that effectively have local monopolies on the supply of organs. These agencies are all nonprofit. They charge prices for the organs they procure that are, on average, just sufficient to cover their costs. At present these agencies do not charge, nor do they pay, any amount for the organ per se; rather, all charges are for the doctors' services and other personnel and equipment costs involved in harvesting and transporting the organ. If a futures market such as the one described here were implemented, these agencies could continue to function much as they do now; the only necessary change is that they would have to pay the administratively determined prices for organs to holders of the rights to those organs—prices that the agencies would then pass on to the recipients of the organs or their insurers along with the other costs of the transplant.

As an alternative, the market elements of such a scheme could be even further attenuated by requiring that the insurance companies resell the organ futures to the government immediately upon purchasing them at a price set by the government. The government could then simply allocate the organs through the existing organ procurement and distribution system without financial charge. Such a system would differ from a full government monopsony of the sort proposed by Schwindt and Vining only in that it would retain private insurance firms as administrators of the actual process of soliciting the organ futures, although this in itself might bring important advantages.

Regardless of the method employed to determine the price for harvested organs, a premium reduction system of the type described here would be practical only if that price were sufficiently high to make the value of the future rights to a policyholder's organs large enough to cover the costs to the insurers of administering the system (the insurers' "loading costs") and still have enough left over to provide a premium reduction to policyholders sufficient to catch their attention. Rough calculations can provide some perspective on the likelihood that this condition will be met. At present the average American has a chance of about 1 in 10,000 of

dying during a given year under circumstances that would render his organs suitable for transplantation.[22] If (for those decedents whose organs are harvestable) the average value of all the harvestable organs in a body were $100,000 (that is, if this were the total amount for which the holder of the futures could sell the rights to the organs upon removal for transplanting), then the annual value of the futures for the average American would be roughly $10. If the value of the organs when harvested were instead $1,000,000, then the futures for a single year would be worth $100. Although these are not large sums, amounts in this range—and especially toward the upper end of this range—could well be sufficient to cover insurers' loading costs and still provide a meaningful premium reduction. Moreover, higher premium reductions could be offered if it were possible (as seems likely) to identify substantial subgroups of the population, such as the elderly, whose organs would not be usable in any event and who could therefore be excluded from the group offered premium reductions.

Supply response. Of course, the principal motivation for adopting a payment scheme such as that just described would be to increase donation rates. A critical question, therefore, is whether it is reasonable to believe that donation rates would in fact increase substantially in response to the offer of insurance premium reductions.

As already noted, most individuals are evidently not in principle opposed to donation; presumably they fail to donate only because of inertia, mild doubts about their preferences, a slight distaste for considering the subject, or the inconvenience involved in completing or carrying a donor card. In this context, it is possible that a relatively modest financial incentive would improve donation rates substantially. The proffered premium reductions would serve to focus the attention of potential donors on the issue and would give them an incentive—or perhaps simply an excuse—for resolving their doubts in favor of donating. Put differently, the premium reductions might not serve so much to compensate people for giving up something of value to them as simply to make it worth their while to incur the transaction costs, both material and psychic, involved in making a decision to donate. In addition, and perhaps of equal or greater importance, because there would be a set of institutions—the insurance companies—with a strong incentive for soliciting donations, solicitation would presumably be far more extensive than at present.

On the other hand, there are several other considerations that might interfere with a strong supply response here.

Reduction of altruism. A common objection to providing compensation in contexts such as this is that it will drive out voluntarism—that is, that individuals

22. The U.S. population is roughly 240 million (U.S. Department of Commerce 1987: 74). It is estimated that between 17,000 and 26,000 people die annually under circumstances that make them potential organ donors (U.S. DHHS 1986: 35).

who would otherwise be willing to donate out of a spirit of altruism will actually be less willing to donate if payment is offered. If this effect were serious and widespread, then the introduction of payment might produce little or no net overall increase in organ supply. The issue has been much debated in the context of blood donation (Titmuss 1971; Arrow 1975). The limited empirical evidence available in that context is ambiguous even as regards the supply of blood, and arguably does not carry over well to the context of organ donation in any case.[23] Thus, the most we can say at this point is that neither logic nor data permit us to conclude at this point whether a payment scheme such as the premium reduction plan described above would be counterproductive because of interference with altruistically motivated donations. Only experimentation is likely to provide clear answers.

Note, moreover, that whether the type of payment scheme described here would be perceived by prospective donors as inconsistent with their altruistic inclinations would presumably depend in considerable degree on the way in which those individuals frame the issue for themselves, and thus in turn on the way in which the choice is presented to them. For example, is the question whether the typical American would be willing to sell the rights to his organs for (say) $40 per year? Or is it whether the typical American would be willing to pay an extra $40 per year in health insurance premiums for the privilege of refusing to make his organs available to save several other persons' lives after he has died? Consider, in this connection, the approach suggested above for employees covered by group health policies at their workplace. As suggested there, it seems plausible that appeals to altruism, community spirit, and financial self-interest could all be combined in a fashion that would be complementary and effective in securing donations.

Note, too, that under an insurance premium reduction scheme organ donors could be permitted to designate that their premium reduction be donated to a charity of their choice rather than refunded to them personally.[24]

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23. For a review of the literature on blood donor motivation and recruitment, see Oswalt (1977). Upton (1973) reports the results of what appears to be the best (though still very limited) empirical study on the subject. In that study, payment of $10 for giving a pint of blood was offered to individuals in two groups: those who had regularly donated blood in the absence of payment, and those who had occasionally donated blood in the absence of payment. The offer of payment significantly reduced donation rates for the first group below a comparable sample not offered payment, while it slightly increased donation rates among individuals in the second group. Though this study does indicate that low levels of payment decrease donation rates for those otherwise strongly inclined to volunteer, it provides no clear indication of the likely consequences of a payment scheme for cadaver organs of the type outlined above, for several reasons. First, the results of the study are consistent with the conclusion that an offer of payment, even at only $10 per pint, to the population at large would bring a substantial increase in overall donation rates. Second, donation rates in the first group may have fallen because of the low level of payment offered, which was surely below the opportunity cost of time and bother for many individuals in the group. Indeed, the offer of $10 in payment may have been taken by many in this group as an indication that the social value of a pint of blood was only $10, and hence it would not be worthwhile even from a social point of view—that is, even in the absence of compensation—for them to take the time to donate. Third, whereas for many individuals there is a very tangible opportunity cost in terms of time and effort to donating blood, the same is not true for donating the right to take their organs after death. Thus modest amounts of payment may produce a much larger response in the latter case than in the former.

24. Another reason offered by Titmuss (1971) for reliance on donations rather than purchases for

Committing not to give. A further potential difficulty with a futures market for organs is that it might remove some people from the donor pool whose organs would be available under the current regime. As noted above, an individual who declines to accept a premium reduction or other payment for the future rights to his organs would presumably be deemed to wish not to make his organs available for transplant. Consequently, his family would not be free to decide to authorize donation upon his death. This is in contrast to the current regime in which, if an individual does not sign a donor card, it is still possible to prevail upon his family to donate his organs after his demise. If individuals in general are less inclined to donate their own organs than to agree to the donation of their deceased relatives' organs, which may be the case, these factors might diminish the advantage of the futures market approach relative to the current regime in terms of supply response.[25] This problem is not confined to a market for organ futures. It arises with any approach, such as the mandatory choice approach described earlier, that confronts living individuals with a clear "yes or no" choice as to whether or not to be a donor upon their death.

Fear of doctors' incentives. A third factor that might detract from an individual's willingness to agree to sell the future rights to his organs is the fear that this will compromise the quality of health care he receives. Once the rights have been sold, there will be somebody with a financial interest in the individual's demise. People might suspect that this incentive could perhaps be brought to bear in some way on the doctors and hospitals responsible for treatment in life-threatening circumstances, rendering them less than zealous in sustaining life when the individual's organs appear harvestable. Though such fears would presumably be unrealistic under any properly regulated regime, they might not be easy to allay.

Net effects. In summary, it is not easy to predict what proportion of individuals would agree to donate in response to an offer of compensation for future rights to their organs. It is at least possible, however (though by no means certain), that

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blood supplies was that the quality of commercially obtained blood was markedly lower than that of donated blood, particularly with respect to serum hepatitis (and, more recently, AIDS). (See also Rose-Ackerman 1985: 945–48.) This argument was apparently important in moving the American blood collection system from one in which (in 1965–1967) 80 percent of all blood was obtained from paid donors (Scott 1981: 191) to one in which virtually all whole blood is obtained from unpaid donors. It has been argued persuasively, however, that the quality of commercially obtained blood would not have been a problem if most states had not passed legislation prohibiting strict liability for diseases transmitted by transfused blood (Havighurst 1977). In any event, it is not clear that similar concerns about quality are applicable to "hard" organs such as kidneys and hearts, where the opportunity for moral hazard on the part of donors seems much smaller.

25. A variant on the insurance proposal outlined above would permit individuals to check one of three boxes on their insurance form: (1) donate and receive a premium reduction; (2) decline to donate; (3) make no decision one way or the other now, but leave the donation decision to the next of kin upon demise. If the latter option is provided, however, then it must be decided whether the next of kin or the deceased's estate should be able to receive compensation for the rights to the organs when they are removed.

overall donation rates would be significantly higher under such an approach than they are, or could easily be brought to be, under the current regime.

Making decisions at the right time. An important advantage of the future contracting approach is that it would encourage decisions to donate when they are least problematic—namely, when they are made by the person whose own organs are involved and at a time when that person is healthy and has the opportunity to reflect at leisure on the matter and discuss it with family, friends, and advisors. In contrast, the existing system, and most of the reforms currently proposed for it, rely heavily on persuading an individual's family to agree to donate the individual's organs in the hours immediately following death. An unfortunate detriment of this approach is that it imposes considerable psychological pressure on both the family and the physician. Although it is sometimes suggested that putting a price on human organs would in some way be offensive to our values (an issue that will be explored in some detail below), it is important to keep in mind that any such moral difficulties with a futures market for organs must be compared with the morality of routinely inflicting distress on families by forcing them to make an emotionally difficult decision in the minutes and hours immediately following the death of a family member and subjecting them to substantial psychological and social pressure to make that decision in favor of donation. Indeed, it is arguably something of a misnomer to call the current organ procurement system "voluntary"; it might be more accurate simply to call it "uncompensated." (To be sure, health care professionals associated with the existing organ procurement system generally do not think of themselves as applying "social pressure" to bereaved families, but rather as "educating" them concerning the "opportunity" to donate—e.g., Broznick 1988.[26] Without some selective insensitivity along these lines and a strong sense of mission, the job would, of course, be much harder to do.)

Paying compensation versus changing tastes. For most individuals, any costs incurred in agreeing to donate their organs upon death are purely psychic; neither they nor their family and friends will experience any material disbenefit as a consequence of the decision. Such psychic costs—whether deriving from a belief that an intact corpse is necessary to achieve an afterlife, or simply from an aversion to the thought of dismemberment after death—are presumably subject to modification through education or changes in prevailing social mores. Thus it is possible that, over time, these costs could be mitigated and that a strong cultural norm affirmatively supporting organ donation could be developed, so that eventually nearly all members of society would experience a strong sense of gratification from donating and would clearly prefer to do so. (Obviously, many people feel this way

26. This is not to deny that there are many bereaved families that find solace and a redeeming sense of affirmative purpose in the opportunity to donate a relative's organs to save another person's life. It is only to suggest that there may be better ways to make this opportunity available.

even now.) With a nearly universal cultural norm of this sort, compensation of any sort for donors could well be superfluous. A payment system would simply incur administrative costs to redistribute income without yielding any important benefits in terms of incentives. Other mechanisms for donation would then be preferable. For example, a true presumed consent system might be established under which organs would be routinely harvested without inquiry unless the deceased or next of kin took upon themselves the affirmative burden of making known their opposition.

It is possible that the present voluntary approach would be more effective than a payment scheme (such as the futures contracting approach described above) in building up such an ethic in the long run. If so, it might be reasonable not to adopt a payment scheme even if in the short run it would lead to a significantly higher rate of donation. This possibility deserves consideration. On the other hand, it is not at all clear that an ethic favoring donation could not be developed nearly as quickly, or even more quickly, in the presence of a modest payment scheme as it could without it. As suggested above, altruism and compensation need not be mutually exclusive, and the increased donation rate resulting from a payment scheme might itself be the fastest way to inure the populace to the concept of routine donation.

In any event, this argument applies only in the case of cadaveric organs; there will presumably always be more than merely psychic costs incurred by living organ donors, to whom we now turn.

Markets for organs from living donors

In theory, it would be much simpler to employ compensation in procuring organs—in particular, kidneys—from living donors than it would be in procuring cadaveric organs. In the past, payment has routinely been made to living donors for replenishable body products such as blood, sperm, skin, and hair (Scott 1981: 179–97). Strong controversy has arisen, however, over proposals to extend payment to kidneys. In fact, as observed earlier, the existing legal bans on organ sales seem primarily to have been inspired by such proposals.

Before assessing the objections that have been offered to purchasing organs from living donors, let us first consider the potential advantages.

Advantages. The chief advantage of using living donors for kidneys is that they offer a source of supply that could easily satisfy 100 percent of the foreseeable demand for transplants. Since there are only about 20,000 cadavers annually from which organs could potentially be harvested, we know that the supply of cadaveric organs is ultimately inelastic: there will be some point beyond which raising the price for organ futures (or pursuing any other strategy) will not appreciably increase supply.[27] In contrast, the supply of kidneys from living donors is potentially

27. Prices might nevertheless be allowed to rise further, beyond the point where they bring additional

highly elastic, since most members of society could be donors and since as prices rise an ever-increasing percentage of the population would presumably be willing to donate. Widespread acquisition of kidneys from living donors therefore holds the promise of saving many lives and avoiding the substantial public expense and private agony of hemodialysis, which (aside from death) is the current alternative to a transplant.

Further, a large pool of living donors could lead to an important increase in the quality as well as the quantity of kidneys for transplant. The long-run success rate of kidney transplants has been closely correlated with the closeness of the match of tissue types between donor and recipient, and there is evidence that this correlation continues to hold even with the use of the new immunosuppressive drug cyclosporine (Cook and Terasaki 1988; but see also Najarian et al. 1988, who find such a correlation only for retransplants). With cadaveric organs, close tissue matching often cannot be achieved, particularly when there must be potentially deleterious transportation of organs over large distances. With a large pool of living donors, however, nearly universal close tissue matching could presumably be accomplished easily. Moreover, transplants from living donors eliminate the critical problems of timing that affect transplants of cadaveric organs, which require that a recipient be located and prepared and the transplant undertaken within hours of the (often unexpected) death of the donor.

Protecting the poor and improvident. For a large fraction of the population, selling a single kidney might be a reasonable decision at prices in a range that demand could support. Donation is evidently not highly hazardous to the donor's health: it has been estimated that the increased risk of death to a healthy 35-year-old from giving up a single kidney is about the same as that involved in driving a car sixteen miles every workday (Hamburger and Crosnier 1968). Many individuals willingly (and, most of us would probably conclude, reasonably) incur risks on this order to achieve savings in personal expenses or to obtain higher wages. Moreover, the fact that living individuals commonly donate kidneys to their relatives also suggests that such transactions are efficient in the economic sense—that is, that the organ is worth more to the recipient than it is to the donor—and thus that there will commonly be a price that will make both donor and recipient better off even in the absence of altruism.

It is often argued that the poor would be the principal sellers in a market for organs, and that therefore such a market would unacceptably exploit the poor for the benefit of the rich. The classical objection to this argument is, of course, that it is a perverse kind of paternalism that prohibits a class of transactions simply because the poor are likely to be the principal sellers, since the result of the pro-

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increases in supply, in order to permit them to serve the rationing functions described later in this article.

hibition is to leave the poor worse off by their own lights: any individual who would agree to sell would evidently rather have the money than have the slightly greater chance of avoiding the death or illness that would result from keeping the kidney. Thus, if society is not willing to give the poor sufficient assets so that they are not inclined to sell a kidney, then society should not refuse to let them sell one of the few assets they have (see, e.g., Andrews 1986; Radin 1987). And, after all, society does not prevent the poor from accepting pay for jobs such as coal mining and meatpacking that carry substantial risk of injury or death. Why should kidneys be different?

One might well conclude that kidneys are not in fact different, and that concerns about exploitation of the poor are misplaced here. But there are at least two reasons why selling kidneys might be thought of as distinguishable from selling one's labor to a meatpacking plant. For one thing, taking a job as a meatpacker is a day-by-day decision that can be abandoned at any point that one thinks better of it. The sale of a kidney, in contrast, is a one-time act that is to a degree irreversible (although the possibility that a donor can get a transplant himself if his remaining kidney fails considerably reduces the degree of irreversibility). This means that the possibility of making a mistake in selling a kidney is much larger than the possibility of making a mistake in taking a job as a meatpacker. One might therefore be concerned that those individuals who would sell a kidney for commercial motives would (as compared with those who held ongoing jobs as meatpackers) contain a disproportionate number of individuals who had acted improvidently—whether from lack of education or intellect or because circumstances made them temporarily and irrationally desperate—and who will come to regret their act (see Annas 1984). This might be reason enough to be concerned about permitting such sales even if all the unfortunate consequences were to be borne only by the individual seller. But those who sell a kidney and suffer health consequences later as a result are also disproportionately likely to be poor enough to have their subsequent medical care provided at public expense, so that some of the costs of the sale will be externalized to society at large.

Kidney sales may also be different from risky jobs in another sense. Suppose that the market-clearing price for kidneys from living donors would be high enough—say, $15,000—to be a serious temptation for a large number of poor people, but still not quite high enough to induce most poor persons to agree to sell. In such circumstances, many of the numerous poor who decide not to sell may feel themselves considerably worse off after making that decision than they would have if never faced with the decision at all. These individuals must, after all, live with the knowledge that they have refused to give something of themselves in return for funds that would be valuable to their family or other loved ones. Conventional economic analysis assumes that persons are always made better off by having more choices, but obviously that is not always true.

In any event, a market for kidneys from living donors would need to be regulated in some fashion to guard against improvident transactions. Presumably one would

not want a situation in which an unscrupulous doctor could induce a drunk to come in off the streets and yield up a kidney on the spot for $50. Many forms of regulation would be possible. A rather heavily regulated regime, for example, might require that only federally licensed agencies be able to purchase kidneys (and might also require that the agencies be nonprofit); that there be a six-month waiting period between the time that the agreement of sale is entered into and the time the kidney is removed, at any time during which the transaction can be rescinded; that sellers must be at least 25 years of age, be examined by a physician and a social worker, and be approved by a consultative panel unconnected to the purchasing agency; and that the price not be below a mandated minimum sum. The question, then, is whether a commercial market for kidneys, even with an appropriate degree of regulation, would so harm the poor and improvident that such a market would be socially unacceptable. As a way to further test one's sensibilities here, consider a system under which the poor would be specifically prohibited from selling their organs—for example, by prohibiting purchases from individuals whose average income for the past three years was not at least 80 percent of median family income in the U.S. (thus cutting persons in the lower 40 percent of the income distribution out of the market).

Moreover, in considering distributive issues, it is important to recognize that the poor and improvident are quite disproportionately represented among those who suffer from kidney failure. If commercial purchase of kidneys from living donors would substantially increase the supply available for transplantation, these groups would therefore gain much of the benefit. The net result might therefore be quite progressive.

In sum, although the issues are difficult, it is not at all obvious that concern for the poor and improvident is a sufficient, or perhaps even a substantial, reason to reject purchases from living donors.

Commodification. It is frequently said—as in the statement from the federal task force report quoted above—that the commercial sale of human organs, and particularly organs from living donors, should be prohibited because it would tend to "commodify" them. It is difficult, however, to find a clear statement of precisely what is meant by commodification or why it is undesirable.[28]

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28. One of the most recent efforts to give content to the notion of commodification appears in Radin (1987). Her analysis, which still leaves the general concept rather vague, becomes most substantive when she discusses the considerations that determine which transactions (at least at this stage of social development) are inappropriate for commodification—i.e., for commercial sales—and which are not (ibid.: 1909–14). These considerations are: improvident sales may make the seller worse off by his own estimation; certain things become "different" (and presumably inferior) things if they are bought and sold; and market transactions will tend to drive out nonmarket (and particularly altruistic) transactions, which for some goods have special value. Unfortunately, Radin offers very little analysis of the second and third considerations—which, as she notes, are closely related.

Normative categories. Perhaps part of the underlying problem here is that as a society we tend to put most transactions into one of two distinct normative categories, which we might label "market transactions" and "nonmarket transactions." (Surely our culture in fact provides for many normative categories that differ on a number of dimensions; the simple two-category model presented here is only meant to be suggestive.) In market transactions, a good or service is exchanged for cash or other valuable consideration under circumstances in which both parties to the transaction enter into it in the expectation that they will personally be better off after the transaction than before. In nonmarket transactions, on the other hand, an individual's willingness to enter into the transaction is governed not by calculation of immediate personal gain but by a variety of other-regarding social mores or norms that the individual feels obliged to observe. Transactions involving the acquisition and care of automobiles tend to be put in the first category; transactions involving the acquisition and care of children tend to be put in the second category. For those transactions that are in the first category, social mores not only permit but in fact encourage individuals to be strongly self-seeking. Thus, if one sells one's used car to a stranger for less than its full market value, one is likely to be called a chump rather than an altruist. For those transactions that are in the second category, on the other hand, narrow calculations of personal advantage are considered inappropriate. If one tires of one's child it is not deemed acceptable—much less praiseworthy—to stop giving it food or to sell it to the highest bidder.

One important characteristic that commonly distinguishes market transactions from nonmarket transactions is that the latter involve substantial external costs or benefits that cannot be internalized without excessive transaction costs. When selling a child, for example, there is a third party whose interests are heavily at stake—namely, the child himself. And, owing to such factors as the child's inability to borrow against future earnings and his imperfectly developed rationality, he is in no position to enter into transactions to protect his own interests. Parents must therefore be led to internalize a set of norms that induce them to provide care for their children whether or not they feel that what they get in return yields them adequate compensation.[29]

A second, closely related reason for using norms of right and obligation rather than market exchange to govern a set of transactions is that the cost of employing market mechanisms would be high relative to the value of the transactions involved. Thus, small transactions among individuals who interact frequently, such as those among friends, family, or workers within a firm (including those between managers and their subordinates), are often not mediated by markets but rather

29. Epstein (1985), focusing on legal rather than moral (i.e., informally enforced) restraints, makes the complementary argument that it is principally a desire to control negative externalities that underlies most efforts to outlaw the alienation of property through sale. (He does not, however, discuss the prohibition on sales of organs.)

by shared norms, since establishing prices for all such transactions would be unduly complex and time-consuming (see Coase 1937).

These two reasons for using morals rather than markets to govern any given set of transactions are fundamentally the same. The question in either case is ultimately whether it would be unduly costly to develop market mechanisms adequate to internalize to the decisionmakers involved all of the important costs and benefits of the transactions.

As has often been remarked, it is advantageous to assign as many transactions as possible to the category of market transactions since this "economizes" on morality. Where the "invisible hand" of the market works well in advancing social welfare, there is no reason to expend the substantial social effort necessary to develop and inculcate a (possibly very elaborate and perhaps rather rigid) set of norms to guide transactions.

Perhaps because our cognitive capacities are limited and because the social costs of inculcating norms are high, the psychological categories to which transactions are assigned tend to be broad and crude. It is not easy for us to consign one set of transactions to the nonmarket category and another seemingly closely related set of transactions to the market category. Moreover, substantial forces of inertia make it hard for us to rearrange our categories. Sometimes changes in technology or social institutions render it feasible to move a set of transactions from the second category to the first—that is, to use markets to handle transactions that were formerly guided by norms mandating a degree of altruism. But the process of undertaking such a shift may be difficult and highly contentious. If individuals were previously socialized to think it immoral to approach a set of transactions from a strongly self-regarding stance, then at first they are likely to find it deeply offensive to see the same transactions subjected only to the mores of the marketplace. Norms, by their nature, are not easily changed.

This inflexibility in our normative categories may help explain the reflexively negative moral response that commonly greets proposals for marketing human organs. There are a number of reasons why individuals might commonly be inclined to feel that giving up a body part to another individual belongs in the category of altruistic nonmarket transactions. There have previously been no markets here to which individuals might become accustomed. To those who have not thought closely about the nature of the risks involved, yielding up a vital organ such as a kidney while still alive may seem like the kind of life-threatening sacrifice (such as attempting to rescue a drowning person in heavy seas) that cannot easily be made the subject of market transactions and that have therefore always been governed primarily by other-regarding norms. For the past fifteen years, for good reasons or bad, our society has sought to delegitimate markets and encourage norms of altruism in the seemingly analogous area of blood donation. And for 25 years we have also been trying to encourage norms of altruism in the area of organ donation itself.

But initial resistance to shifting normative categories should not in itself be a sufficient reason for avoiding change. Transactions can be and have been recategor-

ized when technological changes have made market mechanisms advantageous. For example, we are now quite accustomed to having proprietary institutions market nursing care for the elderly and matchmaking ("dating services") for the young. To take another example closer to the subject at hand, after several decades' experience our society has accepted a thriving market in human sperm brokered by proprietary firms. It would be easy to characterize such a market as deeply offensive to fundamental values involving paternity, sexual relations, responsibility for and identity with one's biological offspring, and the need to make children feel that their relationship with their parents transcends that of mere commodities. And evidently, there was substantial ethical resistance to this market when it was first introduced. Yet over time we have chosen not to so characterize such transactions, but rather to draw the symbolic lines between our normative categories elsewhere so that market transactions in human sperm are not perceived as undermining nonmarket norms in those areas where such norms continue to play a strong functional role.

On the other hand, it is costly to make people upset their received normative categories, and there is no point in doing so unless substantial benefits will result. Moreover, there may be some circumstances in which it is unusually difficult to acculturate individuals to distinguish between different categories of transactions for normative purposes.[30] For example, transplants of kidneys are least likely to be rejected by the recipient's body when there is a close match between the tissue types of the donor and the recipient. This means that transplants of kidneys from living donors within the same family are often the most successful. Most intrafamily transactions are and must remain nonmarket transactions rather than market transactions, however, and thus we are socialized to think that the calculus of the market is inappropriate among family members. Introducing market considerations into one very significant type of intrafamily transaction—that involving transfers of kidneys—might therefore strain the whole moral fabric of the families involved. You cannot extract a high price from your brother for one of your kidneys and then expect him to willingly provide you with extensive moral support for free while you go through your divorce.

Moreover, it may not even be possible to employ market transactions only for kidney transplants *outside* the family without putting severe strains on intrafamily relationships. For example, an individual might feel deeply resentful if subjected to moral pressure to donate a kidney to a family member without compensation when a substantial payment would be forthcoming if the organ were transplanted outside the family.[31] In short, it may be very difficult here to draw lines, whether

30. This problem is apparently what people have in mind when they object to employing markets for a given class of transactions not because market allocation would be inappropriate for those transactions themselves, but for "symbolic" reasons. For discussion in the context of markets for babies for adoption, see Posner (1987: 70–71) and Cass (1987).

31. An analogous problem arises for daughters or sons who have a particular skill—for example,

between transfers of kidneys within the family and other types of intrafamily transfers or between intrafamily and interfamily transfers of kidneys.

It follows that if most kidneys from living donors had to come from family members, it might be best not to try to develop market transactions for kidneys, even among strangers. The rapid development of immunosuppressive drugs, however, has made transplants among unrelated individuals increasingly feasible. As this development reduces the need for intrafamily donations, the costs of using market transactions among living kidney donors—in the form of moral strain on family relationships in general, and perhaps also in the form of reduced intrafamily kidney donations—may decline (indeed, it may already have declined[32]) to the point where they no longer need be considered important.

In any event, it is understandable that, whatever the ultimate merits of a market for human organs, the initial reaction to a proposal for such a market is likely to be one of strong moral opposition. NOTA's proscription of market transactions in organs presumably reflects precisely this type of reaction. Ironically, but perhaps expectably, this ban has been enacted just at the time when such a policy is probably becoming anachronistic, not only for cadaveric organs but perhaps for organs from living donors as well. Before markets for organs were feasible, there was little incentive to outlaw them. Now that such markets seem feasible, the idea of having them offends the norms that developed in their absence.

Altruism as a good in itself. It is sometimes argued that, at least in some circumstances, altruistic transactions have value in themselves to donors as well as recipients, that commercial transactions will tend to drive out altruistic ones, and that therefore commercial transactions should be forbidden in such circumstances (e.g., Titmuss 1971; Radin 1987). But even if we accept that (perhaps for reasons rooted in our heredity) we have a need for altruistic relationships and that commercial sales and altruism are inconsistent, it remains for us to determine for which transactions this is sufficiently important to support the proscription of sales. If such considerations do not justify outlawing a commercial market in care for one's elderly parents—and we evidently feel it does not—then why should they justify outlawing sale of the rights to one's organs, even after death? Other considerations, such as those discussed earlier here, still seem necessary to draw the line between those transactions suitable to commercialize and those which are most suitably used to satisfy our needs for altruism.

Too many organs?

A final, perverse problem that could arise from an effort to employ market incentives to procure organs—whether from living donors or from cadavers—is

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medicine or law—that is in demand by other members of the family, who apply pressure for the contribution of professional time that could be charged for on the market.

32. For somewhat conflicting evidence on this point, see Cook and Terasaki (1988) and Najarian et al. (1988).

that such an approach might be so much more effective than the existing voluntary donation system that it would put extreme pressure on current methods for rationing transplantable organs. Transplants are extremely expensive: a heart transplant costs between $60,000 and $110,000 and a liver transplant costs between $70,000 and $240,000 (U.S. DHHS 1986: 99). Most of these costs are covered by public funds. Nevertheless, at present there are no policies to limit the number of transplants that are performed in the United States. Rather, an effort is made to transplant all organs that are donated. Thus, the rate of donations is the only limit on the number of transplants performed. Because potential recipients considerably outnumber donors, current policy seeks to ration the existing supply to those individuals who will benefit the most from a transplant—such as those who are relatively young, otherwise healthy, and potentially productive (Robertson 1987: 81). Consequently it is arguable that, despite their high cost, most or all of the organ transplants that are performed are justified in the sense that social benefits exceed social costs (although there seem to have been no careful efforts to study the matter).

But if the supply of organs were to increase substantially, society might be faced with a difficult choice. On the one hand, the policy of transplanting all available organs could be maintained. But this might require devoting an extremely large amount of society's resources to transplants. And with a larger supply of organs, an increasing number of recipients would come from among those who would have only a small chance of gaining from the transplant an appreciable number of years of productive life.[33] On the other hand, the government could decide that there are some individuals for whom it will not cover the expense of a transplant even if an organ is available for which there is no other use. Either course might be painful. So long as the number of organs available for transplantation is severely limited, these alternatives need not be confronted. Thus, in a sense it is convenient to have a severe limit on the availability of organs. Perhaps part of the reason that our society has not more aggressively sought ways to increase the supply of organs—including, perhaps, market incentive schemes such as the kind suggested above—is that we are not eager to confront the extremely difficult and expensive problems of allocation that would result if we were successful.[34]

Of course, markets are one potential mechanism for dealing with these problems of allocation, and that is our next topic.

Markets for Allocating Organs

So far we have been discussing a market system simply as a means of encouraging a larger supply of organs. It remains to ask whether a market could also

33. As Schuck (1989) observes, the federally funded kidney dialysis program is already encountering this difficulty.

34. See Calabresi and Bobbitt (1978) for a sophisticated discussion of other respects in which our mechanisms for producing and allocating vital resources, including human organs, are sometimes structured in order to avoid or obscure difficult social choices among strong competing values.

be employed as a means of rationing the supply of organs among potential recipients.[35]

Distributional consequences

A common objection to establishing a market for organs is that it would have the undesirable consequence of channeling most organs to the rich and making them completely unavailable to the poor. There are, however, several reasons to believe that a market approach would not appreciably disbenefit the poor relative to the current system, and that it might in fact considerably improve their access to transplants.

First, and most important, individuals rarely pay for transplants directly out of their own pockets; most transplants are paid for by public and private health insurance plans, and this practice will presumably continue. Thus the distributional issue here, as elsewhere in health care, concerns marketing health insurance, not marketing transplants themselves. Second, doctors' services, hospital services, and drugs will probably always account for most of the cost of a transplant; adding a charge for the organs themselves is unlikely to lead to a quantum increase in the total cost. Thus, those who would be unable to pay for a transplant if there were a charge for the organ would generally also be unable to pay for it without such a charge. Moreover, it is not clear why distributional concerns call for the organs themselves to be allocated on a nonmarket basis while these other items are priced on a commercial basis. Third, distributional issues must be judged relative to the status quo. For example, although there is a disproportionately large number of poor blacks among those individuals who need transplants (U.S. DHHS 1986: 92), anecdotal evidence suggests that the current system of allocating organs through administrative discretion exhibits a substantial bias toward distributing the available scarce supply to prosperous white males. (Oddly, good demographic data on socioeconomic variables such as the income, education, or occupation of organ transplant recipients seem to be unavailable.) Allocation by price, with insurance plans as payers, might actually lead to a more egalitarian distribution. Fourth, even if relatively prosperous individuals are going to end up with most of the organs in any case, as they do under the current nonmarket system, then progressivity might at least be served by making these individuals pay for the organs they receive (whether directly or through increased health insurance pre-

35. In theory, markets could be used to ration demand, but not to encourage supply. The current system of voluntary donation (or one of the proposed variants on that system, such as presumed consent) could be used to procure organs, which would then be collected by government agencies or nonprofit firms (such as the existing organ procurement agencies) and then sold to the highest bidders. The resulting profits could then be used to subsidize any desired aspect of the health care system, including transplants or transplant research. The current system for collecting whole blood has something of this character—the Red Cross, which is the major supplier, collects blood from uncompensated donors and then sells the blood at prices that evidently yield a net surplus (Zimmerman 1981).

miums), and then distributing the resulting funds to a more representative cross-section of the public by compensating organ donors.

Market pricing in the context of insurance

A market approach to allocating supply could potentially yield the same types of efficiency advantages here as it does elsewhere. First, it could help assure that the available organs go to those individuals for whom they have the most value. Second, it could take the pressure off the existing administrative system of allocation, and avoid any biases inherent in that system. Third, it could help equate aggregate supply and aggregate demand—that is, it could help assure that the number of organs harvested and transplanted is that which equates the disbenefit to the marginal donor with the benefit to the marginal recipient. The important question is whether these potential benefits could be realized within the existing system of health care finance, which is characterized by nearly universal health insurance and in which insurance plans would therefore be the principal participants bidding in the market.

At present, government insurance programs pay for nearly all kidney transplants (Schuck 1989). As a consequence, there is presumably little role for market forces in allocating kidneys. The government, which is in the position of a monopsonist, would in any event establish the price for harvested kidneys and allocate the kidneys thus procured, simply as a matter of administrative discretion. However, the government's role in other types of transplants is much smaller. Most heart transplants, for example, have been paid for out of private insurance; public insurance programs have played only a minor role, although that role is now growing (Evans 1987: 73; Schuck 1989). Since there are a number of competing private health insurers, a market system of allocation therefore holds more promise for organs other than kidneys.

Private insurers would presumably treat the cost of an organ the same way they do the other costs of organ transplants or the costs of any other form of medical care covered by their policies. The insurers' overall demand for transplants—and hence the market price for organs—would ultimately be determined by the amounts of coverage that individuals were willing to purchase at premiums sufficient to cover the insurers' costs. This approach has the advantage that the number and nature of the transplants to be undertaken and the aggregate resources to be devoted to them would be determined, in advance of medical crisis, by individuals or their representatives (particularly unions and employers responsible for health insurance plans) in a context that permits them to reflect calmly on the amount of resources they choose to devote to health care in the aggregate and the amount they choose to devote to transplants in particular as opposed to other types of medical care. This is not to suggest that the market can be expected to work as well for organ transplants as it does for oranges and machine screws. But it should work roughly as well for transplants as it does for other forms of costly medical

care. If, as it appears, we are willing to continue to experiment with a market approach to medical care in general in this country—and it is still unclear what that system will look like in the long run, and how it will perform—then it is not clear why we should adopt a nonmarket regime for transplants.[36]

Would market allocation raise the cost of transplants?

It is sometimes objected that establishing a price of any kind for harvested organs, and particularly a market-determined price, would have the unfortunate effect of considerably raising the price of organ transplants, which is already extremely high. This might be true so far as the private costs of transplants are concerned (that is, the out-of-pocket expense to the recipients or their insurers). But these private costs would be much higher than the social cost (that is, the actual cost to society as a whole of foregone goods and services incurred as a result of undertaking the transplants). The reason for this is that most of the price paid for the organs themselves would ultimately go into the hands of the individuals selling the organs (or the organ futures), and thus would simply involve redistribution among members of society rather than a true social cost. Furthermore, the net amount of redistribution involved might be small. If organs were obtained through a futures market operated by health insurers, then the payments for the organs, in the form of reduced insurance premiums, would be broadly spread through the population. Since the prices paid for organs would largely be passed back to the public in the form of higher health insurance premiums (or, in the case of public health insurance, higher taxes), for most people the net financial effect might be largely a wash. And, as suggested earlier, any net redistribution that did result would probably be progressive.

Indeed, to the extent that a market pricing scheme would lead to a more efficient distribution of organs among potential recipients or to a more efficient overall level of transplants, the result of market pricing would be to reduce the social costs of transplants rather than raise them.

Property rights under the existing system

Any market-oriented approach to allocating organs should be evaluated not in the abstract but in comparison to the available alternatives. In particular, such an approach needs to be compared to the allocation system currently in place.

The existing allocation system already provides for property rights of a sort in human organs. In effect, rights to most harvested organs are now governed by something like a "rule of capture" under which the organs effectively become the

36. For an insightful account of the way one insurer, Massachusetts Blue Cross/Blue Shield, has dealt with payment for liver transplants (in the context of a heavy state regulation of transplants), see Havighurst and King (1986).

property of the hospital that harvests them and/or the local organ procurement agency. Since the organs themselves cannot be sold, the only way these institutions can benefit from them is to transplant them themselves and thus create professionally and financially rewarding activity for the surgeons and other health care professionals associated with these institutions. This naturally creates an incentive for hoarding organs locally rather than sharing them with transplant centers elsewhere that might have greater need of them. In short, there is already a market of sorts for human organs, but one in which sale of an organ must be tied to sale of the physician and hospital services involved in its transplantation. (It follows that extending the diagnosis-related group, or DRG, system of payment[37] to organ transplant operations could well be construed as a violation of NOTA, since the difference between the DRG payment that a hospital received and the hospital's actual cost for the operation would effectively be a payment to the hospital for the organ itself. The larger this difference, the stronger the hospital's incentive to secure organs for transplantation would be.)

Allowing health insurers to establish property rights in harvested organs would facilitate the allocation of organs on a national basis rather than a largely local one. Such a policy would also, of course, be likely at first to be seen as threatening by the health care professionals involved with existing organ procurement agencies and transplant centers. In the long run, however, the result might be a significantly larger overall level of transplant activity, a more rational system of organ allocation, and less pressure on physicians and other health care professionals to devote their energies to persuading individuals to donate organs and to making difficult decisions as to who is to receive them. Thus, nearly everyone involved with the current system might stand to benefit in the end.

Conclusion

As our technology and our social institutions have developed, we have found it possible and desirable to use various types of market mechanisms to allocate an increasing range of goods and services that were formerly allocated through the family, charitable institutions, or the state. We are now arguably reaching that stage with human organs for transplantation. It would be foolish to suggest that the market offers a magic solution to the many agonizingly difficult issues involved in organ transplantation. But given the disabilities of the current system for obtaining and allocating organs and the improvements that are at least potentially available by permitting appropriate forms of compensation, the present blanket

37. Under the DRG system, a hospital receives a fixed payment of a given amount for all treatments of a given type, regardless of the actual cost incurred by the hospital in treating any particular individual patient.

prohibition on any form of payment seems extreme. Consequently, there is a good case for reforming federal and state law to permit judicious experimentation with suitably regulated markets both to procure and to distribute human organs.

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Ethical Criteria for Procuring and Distributing Organs for Transplantation

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Abstract. This article provides an ethical analysis and assessment of various actual and proposed policies of organ procurement and distribution in light of moral principles already embedded in U.S. institutions, laws, policies, and practices. Evaluating different methods of acquisition of human body parts—donation (express and presumed), sales, abandonment, and expropriation—the author argues for laws and policies, including required request, to maintain and facilitate express donation of organs by individuals and their families. Such laws and policies need adequate time for a determination of their effectiveness before society moves to other major alternatives, such as a market. In organ allocation and distribution, which have close moral connections with organ procurement, the author defends the judgment of the federal Task Force on Organ Transplantation that the community should have dispositional authority over donated organs, that professionals should be viewed as trustees and stewards of donated organs, and that the public should be heavily involved in the formation of policies of allocation and distribution. Concentrating on policies being developed in the United Network for Organ Sharing, the author examines the point system for cadaveric kidneys, the access of foreign nationals to organs donated in the U.S., and the multiple listings of patients seeking transplants. He concludes by identifying two major problems of equitable access to donated organs that will have to be addressed by social institutions other than UNOS: access to the waiting list for donated organs and the role of ability to pay in extrarenal transplants.

Ethical principles, property rights, and human body parts

Several controversies in biomedical ethics revolve around transfers and uses of human body parts (HBPs). (An HBP is here defined as "an organ, tissue, eye, bone, artery, blood, fluid, or other portion of a human body"—see National Conference of Commissioners 1987.) Developments in transplantation and in reproductive technologies have raised significant questions about the moral rights and obligations of individuals, families, health care professionals, and society at large in the transfer and use of HBPs, including, Who own HBPs? What are the moral limits on treating HBPs as property? What are the philosophical presuppositions of judgments about ownership, especially about the nature of personhood and em-

bodiment? And what are the practical implications of such judgments in the context of relevant moral principles?

Actual and proposed public policies (here defined as whatever governments choose to do or not to do) for organ procurement and distribution often assume answers to these questions even if they have never been directly faced—much less resolved—in a pluralistic society. I will briefly outline a few of these general issues, focusing mainly on general ethical principles and conceptions of property rights in HBPs, before turning to modes of acquisition and distribution of human organs.

For purposes of offering an ethical assessment of policies of organ procurement and distribution, I will appeal to several moral principles or values that have become commonplace in debates in biomedical ethics. They have been widely accepted (with only slight variations) in the policy arena, and I will focus on them as embedded in various policies and practices rather than as grounded in any particular moral theology (e.g., divine revelation) or moral philosophy (e.g., the contractarianism of Rawls 1971). Although my approach loses some of the distance and timelessness provided by abstract ethical theories, it also gains from its appeal to principles that are already operative in public policies and practices and can be invoked to criticize and direct them. Embedded principles are not immune to criticism from the standpoint of ethical theory, and it is crucial to move dialectically between ethical theory and ordinary general and particular moral judgments. My approach to this embedded "common morality" is close to the approach of the common law. I will appeal to principles that can be discerned in our public policies and practices, recognizing that they may be inchoate, incomplete, and even inconsistent at times. This approach can be assessed according to its capacity to illuminate and direct our debates about policies of organ procurement and distribution.

The relevant embedded moral principles are respect for persons, including their autonomous choices and actions; beneficence, including the obligation both to benefit others (positive beneficence) and to maximize good consequences—i.e., to do the greatest good for the greatest number (utility); nonmaleficence, the obligation not to inflict harm; and justice, the principle of fair and equitable distribution of benefits and burdens (Beauchamp and Childress 1983; see also National Commission 1978 and President's Commission 1983). These principles are construed as prima facie binding rather than as absolute or relative—that is, they are binding insofar as their features are present. But since any act or policy may have other features (including the infringement of another principle), they may sometimes be justifiably overridden. However, since they are prima facie binding, they should not be infringed, other things being equal. Although balancing is required, it is crucial to follow a definite procedure of reasoning that shows that the infringement of one principle is necessary to protect another principle, that it would probably protect the principle which is considered stronger or weightier in the situation, and

that the infringement is the least necessary to realize the objectives that are sought (Childress 1983).

In addition to disputes about conflicts among these moral principles, our debates about public policies for organ procurement and distribution involve disputes about the appropriateness of viewing HBPs as property. We often think about property only in commercial terms, but even the donation of HBPs presupposes some conception of property. Of course, there are different ways to view property. If we view property as a bundle of rights, then we must determine who the rights holders are and what rights they have. Much of the debate about the appropriateness of the language of property hinges on different conceptions of rights of ownership and different conceptions of owners. For example, the possible owners of HBPs after an individual's death could be those to whom the individual willed those parts, the family, or the community. Possible rights of ownership include the rights to possess, to use, to exclude, to destroy, and to transfer.

In the nineteenth and twentieth centuries, the common law has recognized the cadaver as "quasi-property," and several courts have recognized the family's "quasi-property" right in the corpse (Office of Technology Assessment 1987; Matthews 1983). The courts have held that families have limited property rights in the corpse and have usually ruled out the right to transfer body parts or use them for commercial purposes. But to say that HBPs are quasi-property or that an agent has quasi-property rights in HBPs may be begging the question, for it is necessary to mount an argument for and against certain rights, including rights of transfer. It is not self-evident that all HBPs, such as organs, tissues, and fluids, should be treated the same way in the social institution of property.

As philosopher Lawrence Becker (1977) emphasizes, there are different levels of justification and criticism of property rights. The first level focuses on property rights in general; the second level involves showing that something (e.g., HBPs) can legitimately be property; the third level involves showing that a particular person has particular property rights in X (e.g., his or her body parts). On each level questions will emerge about what property rights encompass, and on the second and third levels questions will emerge about who has the right to engage in which modes of transfer (or acquisition) of cadaveric HBPs. The justification or rejection of some or all property rights of some or all possible rights holders will hinge in part on the moral principles identified above.

In what follows I will focus on four main modes of acquisition or transfer of HBPs, evaluating them in terms of society's legitimate goal of increasing the supply of organs for transplantation in order to save lives and enhance their quality. Rather than attempt to justify this societal goal, I will assume it, and then attempt to determine which policies of organ procurement are ethically acceptable and ethically preferable as evaluated in light of the prima facie moral principles identified earlier, and which are also politically feasible, especially as suggested by public and professional attitudes. After considering organ procurement, I will turn

to modes of distributing organs, again evaluating them in relation to moral principles, particularly utility and justice (equity or fairness).

Even though I will analyze procurement and distribution separately, their moral connections should be underlined (see Childress 1987). It is obvious that policies of organ procurement have a significant impact on distributional problems. For example, successful organ procurement policies will reduce scarcity and eliminate some problems of patient selection. However, it is less clearly recognized that policies of organ distribution may also have an impact on the success or failure of policies of organ procurement. For example, in a system of organ donation, public perception of policies of distribution as unfair will probably reduce organ donations. Depending as it does on public goodwill, the current system of organ donation is fragile in many respects. (Evidence for this claim will be presented below.) This fragility stems in part from the very factors that have led to fascination with organ transplantation in the media, far out of line with its overall significance in contemporary medicine: the saving of human life through the transfer and transplantation of HBPs from one person to another. Unless this fragility is recognized, proposed public policies of organ procurement may do more harm than good.

Methods of acquiring organs for transplantation

There are four main methods of acquiring (or transferring) HBPs: donation (express and presumed), expropriation, abandonment, and sale. All currently play some role in our society. For example, under our present laws and policies, donation is virtually the only mode of transfer of solid organs; it has become the dominant mode of transfer of blood following a period in which the market approach was used. However, in the acquisition of semen for artificial insemination, sales are common, and in the acquisition of tissues for the development of cell lines, abandonment is also frequent (Office of Technology Assessment 1987). Expropriation is rare and more controversial.

It is not clear that there should be a single method of transfer for all HBPs, partly because of significant differences among the HBPs (e.g., renewability), and it is not clear that any HBP should be transferable in only one way. I will next consider whether solid cadaveric organs should continue to be transferred almost exclusively through some form of donation or whether an alternative mode of transfer could more effectively increase the supply of organs for transplantation without infringing important moral principles.

Express donation. The legal framework for organ procurement in all fifty states and the District of Columbia is the Uniform Anatomical Gift Act (UAGA), which was rapidly adopted with some modifications in the late 1960s and early 1970s (National Conference of Commissioners 1968, 1987). Within the legal framework of the UAGA, individuals may determine what will be done with their

organs after their deaths; in the absence of a valid expression of the decedent's wishes, the family may decide whether to donate the organs. According to Peters (1986), this legal right of individuals to determine what is done with their organs "plausibly rests on the deeper theoretical claim that a person's body is his or her property in a significant sense." Thus the UAGA reversed the trend in several jurisdictions of viewing the cadaver as the quasi-property of the family rather than of the decedent, if there was a conflict between them. Some ethicists, such as Ramsey (1970), were ambivalent about the UAGA, partly because its emphasis on the autonomy of the individual while he or she was still alive appeared to threaten the legal tradition of the family's quasi-property right in the corpse.

Many thought that the UAGA's individualistic framework would generate a large supply of organs because opinion polls indicated that people were willing to donate their own organs after their deaths. A Gallup poll taken in 1968 (around the time of the first heart transplant) determined that 70 percent of the U.S. public would be willing to donate their organs for delivery after their deaths (New York Times 1968). In practice, however, the family, not the decedent while alive, has emerged as the primary donor of cadaveric organs (Prottas 1983, 1985).

The term *donor* needs some clarification. The term has been used in two ways: to refer to the source of the decision to donate, and to refer to the source of the organs. The latter use is really inappropriate unless the source of organs is also the source of the decision to donate. This point becomes particularly important in several current controversies—for example, the controversy surrounding the use of anencephalic newborns as sources of organs. Since anencephalic babies have never had the capacity to make a gift or donation, it is inappropriate to refer to them as donors of organs; they are the sources of donated organs, a very different matter indeed. This point also holds for adult cadavers when the decedent could not or did not make a decision to donate either by signing a donor card or by informing the family of his or her wishes.

Individuals as donors. Few individuals take advantage of the main mechanism for expressly donating their organs, the donor card, or what the UAGA calls the "document of gift." Indeed, there has been a significant decline in the stated willingness of individuals to donate their own organs by signing donor cards. According to polls in the last few years, only 40 to 50 percent of adults are very or somewhat likely to donate their organs after their deaths (Gallup Organization 1983, 1985, 1986, 1987). The reasons cited include lack of thought about it and reluctance to face the prospect of death, but some of the most significant reasons reflect distrust, or limited trust, of the system. Respondents worry that if they sign a donor card, physicians might take premature action to obtain their organs before they are really dead or even hasten their deaths (Gallup Organization 1985). This concern increased as the relationship between patients and physicians became more adversarial during the 1970s (as reflected in part in the increase in malpractice suits). The stated willingness to become organ donors is even lower among groups

(such as blacks) who perceive themselves to be on the margins of the system and to have even less reason to trust it (see Callender et al. 1982; Gallup Organization 1985; Task Force 1986: 38ff.).

In addition, organ procurement teams still consult the family (Prottas 1983, 1985; Task Force 1986); if there is a conflict between the decedent's wishes and the family's, the family tends to win, in part because of unwarranted fears of legal liability (the UAGA grants blanket immunity for good faith actions), because of legitimate fears of jeopardizing organ donation, procurement, and transplantation as a result of negative publicity (the loss of many organs for the sake of the few organs of this donor), and because of the desire to be sensitive to the family's wishes.

If we are to increase express donation by individuals, which policies would be ethically acceptable, ethically preferable, and politically feasible? First, as an expression of the principle of respect for persons, the individual's wishes should be established as determinative in cases of conflict with familial wishes. This priority was intended in the original UAGA; the amended UAGA eliminates any uncertainty about the matter, stating that "an anatomical gift that is not revoked by the donor before death is irrevocable and does not require the consent or concurrence of any person after the donor's death."

Second, as the amended UAGA provides, there should be a clear way for the individual to refuse to be a donor, because the failure to sign or even the revocation of a document of gift is ambiguous. Neither necessarily indicates an intention not to have one's organs donated; each indicates only that one did not express an intention to donate, perhaps because of the fears noted earlier about signed documents of gift.

Third, in addition to providing definite ways for individuals to make and to refuse donations, and recognizing the priority of decedents' wishes whether to donate or not, the UAGA should be amended to allow individuals to designate decisionmakers on their behalf—i.e., surrogates who can express the decedent's values in the circumstances of donation (see Areen forthcoming). There is a parallel in some natural death acts (see Society for the Right to Die 1986) that now allow not only the specification of standards (e.g., "I don't want to be kept alive by X under Y") but also the designation of a decisionmaker who can presumably reflect the agent's values in the situation (e.g., "I designate John or Mary to make decisions about my treatment if I am incompetent to do so"). Similarly, in the context of organ transplantation, individuals may be willing to designate a decisionmaker whom they trust rather than signing a document of gift that might put them at risk at the hands of strangers in large, impersonal, bureaucratic institutions that are eager to gain organs.

Fourth, again keeping in mind the priority of the decedent's wishes, there should be an affirmative obligation on the part of appropriate officials, such as law enforcement officers and firemen, to "make a reasonable search for a document of gift" or refusal by potential sources of organs and to notify the hospital of their findings. The amended UAGA imposes this obligation.

Fifth, routine inquiry that is aimed at individuals, particularly when they enter the hospital, should be eliminated. The amended UAGA states that routine inquiry should ascertain whether the patient being admitted is a donor at the same time questions are asked about insurance. If the patient is not a donor, he or she may be asked about his or her willingness to donate, with the approval of the attending physician. Even though routine inquiry expresses individualism and follows the principle of respect for personal autonomy, the timing is unfortunate and, because of the above-mentioned reasons for reluctance to sign documents of gift, would probably lead most patients to avoid putting themselves on record as donors of organs. Indeed, they might even refuse donation rather than express no decision, thereby precluding the possibility of familial donation. Some have proposed that such an inquiry be made in other settings, which might be more appropriate but would still reflect the undue orientation toward individuals' documents of gift.

Families as donors. In practice, the family has become the main donor of cadaveric organs for transplantation. Even though it is clear that family members (as specified in the UAGA) have the legal authority to donate in the absence of knowledge of the decedent's wishes, it is appropriate to ask about the family's moral authority to donate. If the decedent while competent asked the family to donate his or her organs, it is proper to view the family's action as simply conveying the decedent's wishes, which he or she may have been reluctant to put on a donor card for reasons indicated earlier. In such a case, the decedent may be viewed as the donor and the family as the instrument of that donation. If the decedent while competent did not make a decision or express a preference, the family may still decide to donate. Even if they believe that they are doing what the decedent would have wanted (based on his or her values), they are the donors and the decedent is only the source of organs.

Quay (1984: 923) has argued that "no one, including the state, has any right to make use of a person's cadaver or its parts for research, transplantation, or other purposes, if the deceased has not given his free consent to that use." Quay construes the decedent's failure to donate as a refusal of donation, but the evidence presented above suggests that people do not sign documents of gift for various reasons, often preferring to leave the decision to the next of kin who can reflect their values and protect them against abuse in a situation of serious vulnerability. In this context, a decedent's refusal to block familial donation may even be considered altruistic even though it is not necessarily a decision to donate.

Opinion polls indicate that individuals are more willing to donate the organs of family members and even of their own children than they are to donate their own organs by signing donor cards. In a series of polls, over 80 percent of the respondents indicated that they were very or somewhat likely to donate the organs of family members (see Gallup Organization 1983, 1985, 1986, 1987). A cynical interpretation of these results would be mistaken. When put in the context of the stated reasons for reluctance to sign donor cards, the opinion polls suggest rather that individuals who donate family members' organs can view themselves as buff-

ers or barriers between the untrustworthy system and the potential source of organs. This point is supported by the fact that 63 percent of the respondents to the 1985 Gallup poll approved of the statement "Even if I have never given anyone permission, I wouldn't mind if my organs were donated upon my death." When there is a signed donor card, people cannot see a protective buffer or barrier because the donation in principle, though not in practice, has already occurred unless the donor changes his or her mind before incompetence or death.

Required request. First proposed by Caplan (1984a), required request has now been enacted by most state legislatures, recommended by the revised UAGA, and mandated in federal legislation for all institutions receiving Medicare or Medicaid funds (Martyn et al. 1988). Another term might better stress the features that should be present in institutional protocols for approaching the family of a dead person who is a potential source of organs. For example, the organ procurer could inquire about the decedent's wishes regarding organ donation; if the decedent's wishes are not known, he or she could inform family members of their right to donate and ask them whether they wish to do so. The arguments for required request presuppose a willingness on the part of families to donate and a concurrent unwillingness on the part of physicians and other health professionals in hospitals to notify them of their rights and to ask for donations. The main bottleneck is considered to be the failure to notify families and to invite them to donate a relative's HBPs under the appropriate circumstances (see Prottas and Batten 1988). Even though the reasons for this failure include concerns about harming the family, the family members have a moral and legal right to know they can make a donation of the decedent's organs, and they often report that such a donation was helpful rather than harmful. In these circumstances it is fair to require institutions to work out appropriate mechanisms of notification and request that are in accord with their own particular circumstances.

It is too early to predict exactly how the experiment with required request will work. Even in the face of some physician resentment and resistance, there is preliminary evidence of a substantial increase in tissue donation (200–300 percent) and a slight increase in organ donation (10–20 percent) (Caplan 1988). Arguments have been offered for sanctions to ensure physician compliance, but there is reason to believe that such measures would produce a backlash (Annas 1988). Some critics contend that "a policy of required request creates conflicts of interest at the clinical, psychological, and social/economic levels that produce considerable disvalue" (Martyn et al. 1988). But when carefully examined, those conflicts are avoidable through improved education of professionals or through appropriate procedures, or they are inherent in organ procurement itself, whether under required request or under some other policy (Caplan 1988). Another criticism is that "required request laws represent a further step away from voluntary donations" (Martyn et al. 1988), but this criticism either rests on a conceptual error about voluntariness or misconstrues the situation of request and donation.

Educational programs. In addition to professional education, public education is still needed, even in the context of required request. However, such efforts should be targeted mainly at familial donors rather than at individual donors and at changing attitudes rather than at providing information. To recognize the legal and ethical priority of the individual's wishes to donate (or not) is not to determine the direction and focus of educational policies. Since individuals are more willing to donate the organs of family members and also to have family members donate their organs (even if they have not signed documents of gift), efforts should be concentrated not on educating individuals to be donors of their own organs but on educating individuals to authorize family members to donate and to donate family members' organs. Hence it is important to secure intrafamilial communication of wishes rather than signatures on documents of gift.

Educational efforts must also be directed at restoring trust. However, attitudes of distrust are difficult to overcome and may not be amenable to educational efforts. Effective education of the public (and professionals) about brain death could reduce individual and familial distrust of the system of organ procurement. Many of the sources of distrust lie outside that system itself, stemming instead from perceived problems in the wider health care system. Nevertheless, societal and professional actions to alter the criteria of death, which are so essential to the growth of organ transplantation, may be partly responsible for the distrust. There were warnings in the late 1960s and early 1970s that updating the criteria of death in order to gain access to additional organs for transplantation would lead to a backlash. For example, Ramsey (1970) contended that there is a parallel between the necessity on the practical level of differentiating professional roles in declaring death and transplanting organs (so that the physician involved in the transplant should not determine whether the potential source of organs is dead) and the necessity on the intellectual level of differentiating reasons for updating the criteria for determining death. Criteria of death should be updated, he insisted, as part of the care of the dying patients themselves, not as part of the effort to increase the pool of potential donors of organs. Hence great caution is needed before further altering the criteria of death, even to be able to obtain organs from anencephalic newborns to save the lives of potential pediatric recipients who have end-stage organ failure. As Capron (1987) argues, changing the criteria of brain death—or even creating an exception to brain death—to accommodate the anencephalic may further threaten a fragile system. In addition, it is necessary to educate both professionals and the public that there is only one concept of death, not one for potential sources of organs and another for other people (Capron 1983).

Presumed donation. Presumed consent laws have been adopted in several states to obtain corneas and in several countries to obtain organs and tissues. Sometimes called "routine salvaging of organs" or "routine harvesting of organs," these laws authorize the removal of organs on the basis of the decedent's (and/or family's) presumed consent in the absence of explicit dissent. Such a system of organ

procurement involves "opting out" rather than "opting in." Even though countries retrieving organs on the basis of presumed consent still have waiting lists for renal transplants, they "seem to come closer to meeting their needs for transplant kidneys" than countries that rely on express consent (Stuart et al. 1981). But is a public policy of organ removal on the basis of presumed consent ethically acceptable, ethically preferable, and politically feasible?

One critical question is how presumed consent laws are to be construed. They have been criticized for assuming that organs and tissues belong to the state or society rather than to individuals or families. However, such criticism does not necessarily hold, for such laws could be interpreted as presuming donation rather than as assuming communal ownership of HBPs. Properly understood, presumed donation/consent merely shifts the presumption about an individual's and/or family's wishes in the absence of an express statement of those wishes.

If presumed donation is to be ethically acceptable as a basis for the removal of organs and tissues from a cadaver, it is important to determine the nature of the presumption. If donation is presumed on the basis of a general theory of human values or on the basis of what reasonable people would do, without any reference to this person's (or family's) actions, it is unwarranted. If it is based on what this person would have done if asked, it is more acceptable, but still problematic. If, however, it is based on a construal of this person's (or family's) wishes as silently expressed, it can be defensible under some conditions. Perhaps the best way to explicate this approach is to view it as tacit consent rather than as presumed consent.

There are several varieties of consent, and it is important to understand how presumed consent fits on the spectrum of possibilities. The paradigm case of consent is express consent, and it is most prominent in the doctrine of informed consent in therapy and research as well as in the UAGA framework of organ donation. Such express consent creates rights in others. Implied or implicit consent is not expressed but is inferred from other actions, even though the consenter may not have understood or intended such an implication. By contrast, tacit consent, appealed to by John Locke, among other political philosophers, is consent that is expressed silently or passively by omissions or by failures to indicate or signify dissent. As Simmons (1976) notes, under certain conditions, the failure to dissent or to object constitutes tacit consent. The potential consenter must be aware of what is going on and know that consent or refusal is appropriate, must have a reasonable period of time for objection, and must understand that expressions of dissent will not be allowed after this period ends. He or she must also understand the accepted means for expressing dissent, and these means must be reasonable and relatively easy to perform. Finally, the effects of dissent cannot be "extremely detrimental to the potential consenter." Some of these conditions ensure the consenter's understanding; others ensure the consent's voluntariness. When these conditions are met, the potential consenter's silence may be construed as tacit consent. Such consent may

be ethically valid in some circumstances. One major question to be addressed is whether society should structure the transfer of HBPs to include tacit consent as well as express consent.

In principle, presumed donation could be an acceptable basis for organ removal. The major problem is that for presumed donation to be ethically valid, it must satisfy very rigorous standards. Silence may only indicate a lack of understanding of the means of dissent or of the proposed course of action; hence, vigorous public education would be required, along with easy ways to register dissent. Uneasiness about what silence means may account for the similarity of practices in various societies, whatever their legal structure (Prottas 1985). For example, in countries with presumed consent legislation, professionals regularly ask the family (Caplan 1984b). Finally, ethically acceptable presumed donation may not be more cost-effective than enhanced and redirected educational efforts in the context of the UAGA, along with the other legal and policy changes proposed above.

Another possibility is to approach the family on the basis of the decedent's presumed donation rather than to view it as the decedent's legally valid and sufficient donation. Physicians and other health professionals would probably find it easier to approach the relatives of a dead person with a presumption about the decedent's preferences, as established by tacit consent. For example, professionals could approach the family by saying, "Since John didn't dissent, we would like to remove the organs; do you have any objection?" In short, presumed donation, in the form of tacit donation, could provide the basis for a valuable ritual in a difficult, often tragic set of circumstances (Muyskens 1978). However, there is no evidence to suggest that this psychological advantage for professionals would translate into significant changes in organ donation.

In addition to the stringent conditions that would have to be met for valid presumed donation, some have argued for the ethical preferability of a system of express donation in order to symbolize and build a community of altruistic concern among strangers (Ramsey 1970). However, a policy of presumed donation rests on passive altruism, and it does not preclude active altruism. Nor, as I have argued, does it presuppose that HBPs belong to the state. Final control still rests with the individual (and perhaps the family).

Nevertheless, there is a serious difficulty with presumed donation. Although a legal policy of presumed donation could possibly have been adopted in the late 1960s, it is not politically feasible now. In one Gallup poll, 86.5 percent of the respondents indicated that they would be opposed to legislation that would give doctors "the power to remove organs from people who have died recently but have not signed an organ donor card without consulting the next of kin" (Gallup Organization 1985). The existence of laws authorizing the removal of corneas on the basis of presumed consent alone is somewhat puzzling. They have survived constitutional challenges in some states, even when they do not require notification of or consent from the next of kin, and they have been effective. For example,

substantial increases occurred in cornea transplants in the few years after such legislation in Georgia (from 25 in 1978 to over 1,000 in 1984) and Florida (from 500 in 1978 to over 3,000 in 1984) (see National Conference of Commissioners 1987). It is possible that presumed consent laws endure without major vocal opposition because of different views about different HBPs—corneas versus solid organs—and because the public is largely unaware of these laws, even in the dozen or so states where they exist. If the latter is the case, as I suspect it is, presumed donation is not ethically valid because of a lack of understanding on the part of the "donors" who are allegedly "donating" by their silence. Under such circumstances the policy is actually one of expropriation masquerading as presumed consent.

Finally, a policy of presumed donation at this time would probably reduce rather than increase the number of donated organs. Although this claim may appear at first to be counterintuitive, it rests on the evidence about the distrust of the system that potential donors have registered in some polls as the major reason for their reluctance to sign donor cards. In a system of presumed donation, it is highly probable that such attitudes of distrust would lead individuals to take affirmative actions to remove themselves from the list of presumed donors. Such actions would prevent familial donations and, under current circumstances, reduce the number of donations.

Expropriation. The public health justifies autopsies in some cases, even against the conscientious objections of adherents of religious groups. There has been vigorous debate about whether some HBPs, such as pituitary glands, can be removed in the course of autopsies. Jonsen (1988) recently condoned salvaging organs even against the will of the decedent and the family, arguing that the primary and secondary purposes of consent are either irrelevant to or insignificant in the context of organ salvaging. According to Jonsen, the primary purpose of consent is to protect the moral autonomy of persons, allowing them to govern their lives in terms of their own values and to protect themselves from harm and exploitation, but this purpose is "no longer relevant to the cadaver which has no autonomy and cannot be harmed." The secondary purposes of consent include respecting the beliefs that the decedent held while alive or observing cultural practices about burial; however, these secondary purposes "would seem to yield before the significant value of therapy for those suffering from serious illness. . . . The genuine possibility of significant benefit to others overrides any secondary purposes that consent and permission might have" (ibid.: 219).

Although Jonsen's approach merits careful consideration, it fails to see that people can be wronged even when they are not harmed (e.g., by having their will thwarted after their deaths), and that sociocultural practices of disposal of the body remain very important for various communities, including the family and religious communities. Even if respect for autonomy, like all other principles, is only prima facie binding, it cannot be justifiably overridden unless there is no acceptable al-

ternative. In an emergency (similar to a wartime policy of conscription) it is possible that a justification could emerge for the forced removal of HBPs for transplantation against the will of the decedent and his or her family. However, conditions for an emergency are also very stringent—the society must be in imminent danger and lack alternatives (see Walzer 1977). It is not clear that expropriation of cadaveric HBPs can be justified to benefit other individuals by preventing their deaths. And there are acceptable and preferable alternatives that need further experimentation and implementation. Furthermore, in view of other public responses, there is little reason to believe that this method of acquisition would be politically feasible.

Abandonment or failure to claim bodies and HBPs. Another mode of transfer of tissues, fluids, and sometimes organs is abandonment, or failure to claim bodies and their parts. For example, patients simply abandon their excised organs, tissues, blood, urine, etc., which may then be used by researchers, at least under some conditions. This mode of transfer has been the subject of some dispute—for example, in the case in California in which a patient's spleen, which was removed with his permission in a therapeutic procedure, was subsequently used, without any notice to or consent from the patient, to develop a profitable cell line.[1] Nevertheless, this mode of acquiring organs appears to characterize the unclaimed body statutes or coroner's statutes that authorize the removal and use, including transplantation, of organs and tissues. In one recent case in California, controversy arose when a man's heart was transplanted after he died unexpectedly and no one identified him or claimed his body for over twenty-four hours (New York Times 1988). In principle, this mode of acquisition of HBPs will be limited, and it will not significantly increase the supply of organs for transplantation. Furthermore, strict rules should be established to make sure that the body is actually unclaimed—i.e., abandoned. (I will not here address the question about removed parts, tissues, and fluids from living patients, whose expectations about their disposal or use are certainly relevant to a judgment about whether a transfer is validly effected.)

Sales. The original UAGA did not prohibit the sale of organs because the Uniform Commissioners on State Laws "believed that it was improper to include an absolute bar to commercial relationships and concluded that this would best be handled at the local level, by the medical community" (Ramsey 1970). In part in response to proposals to broker human kidneys for transplantation, some states in the 1980s have passed laws to prohibit the sale of organs (Virginia Law Review 1985), and the 1984 National Organ Transplant Act[2] made it "unlawful for any

1. Moore v. Regents of the University of California, Cal. App. 2d (1988) (88 Daily Journal D.A.R. 9520).
2. Pub. L. No. 98-507.

person to knowingly acquire, receive, or otherwise transfer any human organ [defined as human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin and any other human organ specified by the secretary of Health and Human Services by regulation] for valuable consideration for use in human transplantation if the transfer affects interstate commerce." (This federal statute limits the prohibition to "human transplantation," whereas the original UAGA covered education and research as well.) The amended UAGA now also prohibits sales or purchases of cadaveric organs. It does not cover sales by living vendors unless the "removal of the part is intended to occur after the death of the decedent."

Earlier transfers of blood in the U.S. often included financial transactions. It has been argued that the shift away from the transfer of blood by sales reflected "sentiment against tissue sales" (Steinbrook 1981). However, the fundamental reason for the shift away from the transfer of blood by sales—even though blood plasma and some blood products are still sold—was not widespread moral revulsion, but rather cogent arguments that the commercial system in blood was relatively ineffective, inefficient, and dangerous (see Titmuss 1971). The danger mainly involved health risks to recipients (e.g., from hepatitis). Even in his argument against the sale of organs, Ramsey (1970) did not oppose the sale of blood by living vendors on intrinsic grounds; because blood is renewable, it is qualitatively different from organs. Similar points could be made about the sale of semen, skin, bone marrow, sweat, and urine—at least two of which (skin and bone marrow) are not subject to sale for transplantation under federal legislation.

Following a suggestion by Mavrodes (1980), it is possible to locate the sale of HBPs in two contexts: the sale of various goods and the transfer of body parts. In the first context, the question is what is morally problematic about the sale of human body parts among the various goods that are transferred for money; in the second context, the question is what is morally problematic about the sale of HBPs among the various ways to transfer them. One response is that people do not "own" their body parts and thus should not be able to sell them. That response fails to offer an account of how people may "give" or "donate" what they do not own. Another possible response is that people have only quasi-property rights for disposal of the body and its parts, but this answer begs the question unless it also indicates why property rights in HBPs should be limited to donations, rather than also encompassing sales.

Arguments for permitting or even encouraging the transfer of organs and tissues by sales focus either on increasing the supply of organs for transplantation or on respecting people's freedom of choice. The main rejoinder to the first argument is that there are other effective, ethically acceptable, and even ethically preferable ways to increase the supply of organs. The current system of procuring organs through gifts by individuals and their families has generated a substantial number of organs for transplantation (e.g., over 8,900 kidneys in 1987), and several policies have been proposed and some have been implemented (e.g., required request) to increase the system's effectiveness. It would be ethically and politically unwise

to convert the system of donation into a system of sales until these policies have been given a chance to work, in part because transfer of organs by sales would be costly, would probably drive out many donations, and could have serious effects on our conception of personhood and embodiment by promoting commodification (see below). If a system of donation with various modifications proves to be insufficiently effective, then transfer by sales could be tried, even though it would not express the value of altruism that leads many to favor the gift relationship.

In response to the second argument that a market in organs would respect personal freedom, several rejoinders can be made on the basis of the principles of respect for persons, beneficence, nonmaleficence, and justice. First, there are the risks to living vendors or to others whose parts may be transferred by vendors after being killed or allowed to die. Second, there are questions about the vendors' lack of voluntariness, especially if they are poor, economically vulnerable, and subject to exploitation. Even if the risks could be reduced for living vendors (e.g., by not allowing them to sell a kidney) or for sources of HBPs (e.g., by making certain that they were not killed or allowed to die in order to provide a source of revenue) and their voluntariness could be established, opponents insist that a commercial market in organs and tissues is abhorrent to our system of values because it treats human bodies and their parts as commodities (May 1985; Wartofsky 1981). In examining the justification of specific property rights, including commercial rights in the body, Becker (1977) notes that "reform of property laws is quite rightly seen as a matter which could affect the dispositions to achieve, to work, to compete, to cooperate, and to give help to others; it could also influence the pace, mobility, complexity, and (for lack of a better word) humaneness of social life." These considerations, he contends, generate the most potent objections to commercial rights in HBPs.

Even if selling some HBPs, such as solid organs, would be potentially dehumanizing to the society, there is debate about whether dehumanization results from the sales of all human biological materials, including surplus tissues and fluids (e.g., hair and urine) and renewable tissue (e.g., blood). It may even be plausible to view the sale of renewable tissues as the provision of a service, as some state laws have construed the sale of blood, rather than as a commodity (Office of Technology Assessment 1987). In addition, some proponents of a market would distinguish living vendors from cadavers and exclude situations in which a conflict of interest existed (e.g., the sale of aborted fetuses or fetal tissues). Furthermore, it would be possible to distinguish types of valuable consideration, such as direct payments and indirect incentives. For example, could the line be drawn between direct payment and coverage of a donor's medical expenses, compensation of a living donor's lost wages, and payment for the burial expenses of a deceased donor? In short, through various distinctions, it may be possible to accommodate some types of transfer of some kinds of tissues for valuable consideration without major ethical costs.

The equitable distribution of donated HBPs

When individuals and/or their families donate HBPs, who owns the donated HBPs? Do the new owners have unlimited property rights or dispositional authority over those HBPs? Apart from donations to designated donees (as in the case of living donors of kidneys), most organs are donated for distribution to patients in need. The question of the locus and limits of dispositional authority over donated organs often lurks behind debates about particular policies of allocation and distribution even when it is not directly raised and faced.

Community ownership of donated organs. The federal Task Force on Organ Transplantation (1986) held that donated organs belong to the community, and this fundamental conviction undergirded all of its "recommendations for assuring equitable access to organ transplantation and for assuring the equitable allocation of donated organs among transplant centers and among patients medically qualified for an organ transplant."[3] From this perspective, organ procurement and transplant teams receive donated organs as trustees and stewards for the community as a whole, and they should determine who will receive available organs according to public criteria that have been developed by a publicly accountable body with public representation and that reflect principles of justice as well as medical standards. Donations of organs cannot be expected unless there is public confidence in the justice of the system of organ distribution.

There are some unresolved ambiguities about community ownership in the formation of public policies regarding organ allocation and distribution. The federal task force's final report urged that "donated organs be considered a national resource to be used for the public good." This claim immediately provokes the question whether donated organs should be viewed as belonging first to the local community where the organ was retrieved or to the national community. Even though different answers may not lead to different policies, they certainly involve different presumptions and create different problems. If the relevant community of donation is the national community, then that community has the right to assign the organs; because of logistical problems and the importance of incentives for procurement and donation, it may allow the organs to be used in the local community or region if possible, requiring sharing only under special circumstances. An alternative approach starts from local (or state or regional) ownership of donated organs, even if the local community may have to share under some circumstances.

The Michigan Transplant Policy Center (1987) presented the case for federalism in organ sharing against (what it considered to be) the task force's recommendation of a "purely national system." The Michigan center supported a federal system—that is, "state or regional distribution systems which are federally regulated and then linked by a national network for distributing highly sensitized, pediatric, or

3. *Id.*

excess organs as opposed to a system that is, in all important respects, national." The document's arguments for a federal system focused on efficiency through increased participation, organizational lubrication, and fine tuning; on justice that may be threatened when states or regions that are more conscientious and efficient in organ procurement have to share with others; on flexibility and research; and on personal care. The Michigan report tended to downplay the importance of human leukocyte antigen (HLA) matching of donor to recipient, which the federal task force considered essential in its recommendation of a policy of mandatory sharing of six-antigen matches or zero-antigen mismatches.

The United Network for Organ Sharing (UNOS) was established as the national Organ Procurement and Transplantation Network (OPTN) under the terms of a contract developed largely out of the federal task force report, and its philosophy is not unambiguously national rather than federal. Indeed, lack of clarity about its guiding philosophy affects many UNOS debates about procedural and substantive policies, insofar as they concern the relations among local, regional, and national communities.

Just procedures and standards. Whether the system is national or federal, two issues of justice will be central: just procedures for the formation of policy, and just substantive standards of distribution. Justice may be defined as rendering each person his or her due, and it includes both formal and material criteria. The formal criterion of justice is similar treatment of similar cases, while material criteria specify relevant similarities and dissimilarities among people and thus determine how particular benefits and burdens will be distributed. There is debate about the moral relevance of various material criteria, such as need, merit, societal contribution, status, and ability to pay. Different theories of justice tend to accent different material criteria; however, some of these criteria may be acceptable in some areas of life but not in others.

A fundamental issue for organ transplantation is determining which material criteria are justifiable for the allocation and distribution of donated organs. The federal task force (1986) contended that several material criteria could be ruled out as unjustifiable, including discrimination among patients on the basis of race or sex or favoritism or bribery. Beyond excluding such criteria as irrelevant and pernicious, the task force argued for the relevance of general criteria of patient need, probability of successful transplantation, and time on the waiting list. A major task for UNOS is to develop policies to specify these criteria for operational purposes.

Justice involves procedural as well as substantive matters. Particularly where there is debate about appropriate medical criteria (e.g., whether urgency of patient need should have priority over the probability of successful outcome of transplantation), fair and equitable procedures of rule setting are indispensable. Then what is due individuals or groups is determined by the rules that have been fairly adopted. In organ transplantation, the conviction that donated organs belong to the community, not to medical professionals, implies public participation in the formation of policies to govern the distribution of donated organs (Task Force

1986). Rather than discuss these issues of justice in the abstract, I will focus on several procedural and substantive questions faced by UNOS.

The point system for cadaveric kidneys. Although UNOS has developed point systems for the allocation of hearts and livers as well as kidneys, I will concentrate on kidneys for illustrative purposes. The UNOS point system for cadaveric kidneys, built on a proposal by Starzl et al. (1987), requires that cadaveric kidneys be offered to patients on the local waiting list (defined as either the individual transplant center recipient list or a shared list of recipients within a defined procurement area) in descending order, with the patient with the highest number of points receiving the highest priority. Points are assigned according to time on the waiting list (maximum of 10 points); quality of antigen match (2 points for each antigen matched, for a maximum of 12); panel-reactive antibody (1 point for each 10 percent panel-reactive antibody, for a maximum of 10); medical urgency, which is usually not granted if dialysis is feasible (maximum of 10 points); and logistical score, based on ease and rapidity of performance of the transplant (maximum of 6 points). With the approval of the UNOS organ procurement and distribution committee and the UNOS board of directors, a local list may assign different points to the criteria identified above. When a cadaveric kidney is voluntarily released from local (or regional) allocational systems, the UNOS Organ Center will allocate it regionally and then nationally according to the point system just identified. No points are awarded for panel-reactive antibodies, but the national list will print the recipients with the same point values in descending order of peak panel-reactive antibody percentage. Another requirement is that blood group O kidneys be transplanted only into blood group O patients except where there is a six-antigen match (see UNOS 1988c).

Each potential recipient must be listed on the national UNOS computer list, and each donated kidney must be entered into the UNOS computer system to determine whether a potential recipient anywhere in UNOS has a compatible blood group and is matched on all six antigens with the donor organ. If such a match exists, the kidney must be sent to that patient, and in the event of more than one six-antigen match, the kidney will be assigned on the basis of the point system already identified (ibid.).

With the exception of the length of time on the waiting list, the criteria listed above are medical in the sense that they involve medical techniques used by medical personnel and influence the likely success or failure of the transplant. However, as medical criteria, they are not value-free or value-neutral (Brock 1988). The vigorous debate about how much weight each criterion should have is only in part technical and scientific (e.g., the impact of HLA matching); it is to a great extent ethical. Some factors, such as quality of antigen match and logistical score, focus on the chance of successful outcome; both medical urgency and panel-reactive antibody focus on patient need, but in different ways; and time on the waiting list introduces a nonmedical factor, even though it may overlap with panel-reactive

antibody because sensitized patients tend to wait longer for transplants. The points assigned to these various factors thus reflect value judgments about the relative importance of patient need, probability of success, and time of waiting.

As the federal task force (1986: 88ff.) argued, "Because donated organs are a scarce resource, policies to resolve conflicts between equity and efficiency that arise in the distribution of organs should be determined by a broadly representative group that includes patient, community, and ethical perspectives, as well as those of the medical professionals directly involved." This public process must also consider whether criteria that are allegedly based on medical utility (maximization of welfare among patients suffering from end-stage kidney failure) inappropriately incorporate criteria of social utility (maximization of social welfare by selection of socially valuable recipients) and thus infringe standards of justice. Some criteria, such as age, social network of support, and lifestyle, may reflect medical utility, social utility, or both (Task Force 1986; Childress 1987).

Foreign nationals. Another major issue surrounds the task force's recommendation that "donated organs be considered a national resource." The issue of geographical boundaries is international as well as intranational. Of the approximately 6,000 cadaveric kidneys transplanted in the U.S. in 1985, 300 were transplanted into nonresident aliens who had come to the United States for medical care, and 200–250 additional kidneys were shipped abroad for use in other countries (U.S. DHHS 1986).

The debate about transplanting organs into foreign nationals and about exporting donated organs invokes various moral principles as well as different convictions about the ownership of donated organs. Some proponents of physician discretion in the selection of patients argue that the ideal of medical humanitarianism precludes the use of such criteria as national residence. In addition to noting that this ideal is already compromised in various ways, critics of physician discretion note that the distribution of donated organs is not merely a matter of medical humanitarianism. If donated organs belong to the community and procurement and transplantation teams only serve as trustees and stewards of donated organs, then the debate is about social rather than medical humanitarianism (Childress 1987).

The most vigorous and divisive debates on the federal task force centered on the access of foreign nationals to cadaveric organs in the U.S. Members of the task force attempted to balance principles of beneficence (expressed as compassion and generosity), fairness, and efficiency, particularly in the avoidance of kidney wastage. There was little interest in excluding nonresident aliens altogether. Rather, the debate focused on whether to adopt a policy of U.S. citizens and residents first—sometimes called "Americans first"—which would allow some nonresident aliens to be placed on waiting lists but would not allow them to receive any particular donated organ unless no U.S. citizen or resident could benefit from it, or whether to adopt a ceiling on the number of nonresident aliens on the waiting list, but according equal treatment to everyone on the list, regardless of national res-

idence. The task force voted to accept the first policy for hearts and livers and the second policy for kidneys, recommending a ceiling of 10 percent until the matter could be reviewed by the OPTN.

The majority of the task force distinguished between these two policies on the grounds that kidneys are not as scarce as extrarenal organs and dialysis is usually possible as a backup or an alternative to transplantation in the treatment of end-stage renal failure. However, eight members of the 25-member task force dissented from the recommendation for renal organs. Opposition arguments invoked claims that it is unfair to deny or delay access to donated organs for members of the national community of donation and unfair to use taxpayers' money to procure kidneys that are distributed to nonresident aliens (Task Force 1986). Furthermore, critics charge, such a policy would cost taxpayers in other ways because, for example, each kidney transplant performed on a Medicare beneficiary in 1985 would have saved the Medicare system an average of $62,000 over a five-year period. Thus, if 275 of the estimated 300 cadaveric kidneys that went to foreign nationals in 1985 had gone to Medicare recipients, the system would have saved approximately $17 million over a five-year period (U.S. DHHS 1986).

Brock (1988) has argued that the division on the task force suggests two approaches with "considerable plausibility" that could be adjudicated through a public process. The UNOS board made an effort to determine public opinion in several ways—by involving the public on the UNOS board and on the committee that analyzed the options and recommended a policy, through public comment on the proposed policy, and through a public opinion poll. The opinion poll was considered important because of the claim that when members of the public "learn that foreign nationals receive organs instead of U.S. residents and that they generally do so in a shorter period of time, they begin to question the fairness of that system and may very well become less inclined to donate. Indeed, in some communities where there has been much publicity about foreign nationals receiving transplanted kidneys, there has been a subsequent reduction in donation levels" (U.S. DHHS 1986: 10). The UNOS committee commissioned the Battelle Human Affairs Research Center and the Gallup Organization to conduct a poll of U.S. public opinion. That poll, conducted by telephone in January 1987, indicated that there is no clear majority opinion regarding whether domestic patients should receive preferential treatment over nonresident aliens in the U.S. for organ transplants (UNOS 1988a).

After reviewing various arguments, UNOS adopted a policy that establishes some limits and directions but relies mainly on a procedure of accountability in the transplantation of nonresident aliens. The policy requires UNOS members to charge the same fees for nonresident aliens as for domestic patients, to treat all patients accepted on transplant waiting lists according to UNOS policies for the equitable distribution of organs, and to arrange any exportation of organs through UNOS only after it has been impossible to find a suitable recipient in the U.S. or Canada. Accountability is established in several ways. On the local level, UNOS

member centers that accept nonresident aliens on their waiting lists are expected to establish a mechanism for community participation and review. On the national level, the UNOS committee on foreign relations has a right to audit all transplant center activities relating to the transplantation of nonresident aliens and will automatically review any center that has more than 10 percent of its transplant recipients from foreign nationals (UNOS 1988a, 1988c).

Multiple listings. The several shifts on multiple listings by the UNOS board in 1987 and 1988 reflect in part its uncertainty about whether its underlying philosophy is national or federal and in part disputes about the ranking of liberty in relation to equality. After voting in August 1987 to permit multiple listings by patients, in January 1988 the UNOS board voted to prohibit multiple listings. On 5 February 1988, in accordance with its new procedure for public involvement, UNOS published a policy proposal statement on the listing of patients on multiple transplant waiting lists (UNOS 1988b). After receiving public comment and conducting a public hearing in March, the UNOS board voted to continue to permit multiple listings while appointing a committee to examine the matter more carefully and fully.

It has been argued (Smirnow 1988) that the UNOS decision to permit multiple listings stems from another UNOS policy that allows an institution first option on the use of the donated organs it retrieves, except in the case of a six-antigen match between the donor and a patient on the national waiting list. In this context, patients who are knowledgeable and who can afford to travel may seek to be placed on as many transplant waiting lists as possible. As Smirnow (1988) puts it, "If the donor organs weren't going to be shared, the patients would be."

Not only is there the question of the community of ownership or dispositional authority, there is also the tension between liberty and equality as standards of equitable access to organ transplants. The dominant argument for permitting patients to be on more than one waiting list stresses maximum freedom of choice and access; subordinate reasons include the facts that some patients live in different parts of the country at different times of the year and that the local transplant team may be too busy or too tired to perform the procedure when an organ becomes available.

The main argument against multiple listing centers on the unfair advantage it provides for the patient waiting on several lists. In an oversimplified example (assuming a purely local sharing system and equal medical factors), the UNOS (1988b) policy proposal against multiple listings noted that if there were two local lists (A and B), each with 100 patients, each patient on list A or B has a 1 percent chance of receiving any available organ. But if 10 of the patients on A's list are also on B's list, then B has 110 patients and each person on B's list who appears only on that list has only a .9 percent chance of receiving an organ. The 10 people on both lists have increased their chances of receiving an organ to 1.9 percent.

In addition, permitting multiple listings favors wealthy and mobile patients over others, may lead to less effective patient care, may result in variations in tissue typing, and may result in increased expenditures for testing and patient workup that may be borne by the taxpayer under Medicare. Even under the prohibitive policy, patients could choose their center and their physician and would not be restricted to their geographical residence.

An unresolved question is what should be done about patients who may have entered several lists in good faith prior to the adoption of a policy of single listing. The UNOS board's proposed policy of prohibiting multiple listings rejects any "grandfather" clause for such patients on the grounds that the concern for promise keeping and fairness to them is outweighed by the claims of justice of those who are disadvantaged by multiple listings.

Formation of waiting lists. Two final areas of concern about equitable access probably cannot be directly addressed by UNOS and will require attention from other social institutions. First, UNOS policies to ensure patients equitable access to organ transplants do not ensure equitable access to waiting lists for organ transplants; they address only selection from those lists to receive a particular donated organ. There is evidence that women, minorities, and low-income patients do not receive transplants at the same rate as white men with high incomes. The primary source of the unequal access does not appear to be in the decisions about who will receive donated organs but rather in the decisions about who will be admitted to the waiting list (Task Force 1986; Eggers 1988; Kjellstrand 1988; for differential referral rates among centers, see U.S. DHHS 1987). More research will be required to determine the extent to which unequal access to kidney transplantation, for example, hinges on patient choices and legitimate medical factors rather than on physician sequestration of patients in dialysis units, physician failure to inform and refer some groups of patients, or bias in the selection of patients seeking admission to waiting lists.

Ability to pay. A related concern of equitable access is the so-called green screen for patient admission to waiting lists, particularly for heart and liver transplants. Although the criterion of ability to pay, whether directly or through third-party payers, has been largely eliminated in the end-stage renal disease program, it remains central in transplantation of hearts and livers, which are covered by some insurance and Medicaid programs but only in very restricted cases by Medicare. Because the federal program has been so limited, much of the burden has fallen on the states. Thus, Oregon's decision not to provide Medicaid coverage of organ transplants other than kidneys and corneas has received considerable attention in the media (Welch and Larson 1988).

Two major arguments have been offered for increased federal funding, at least as a last resort, for extrarenal organ transplants. The first argument focuses on the continuity between these organ transplants and other procedures that are already

covered by society or that should be covered by society under its putative obligation to provide an adequate level of health care (President's Commission 1983). According to this argument, these extrarenal transplants are comparable in both efficacy and cost to other procedures that are routinely covered or that should be covered as part of society's obligation to its citizens. This argument is accompanied by evidence that heart transplants and liver transplants are comparable to the other accepted or acceptable procedures. In response to worries about cost containment, defenders of public funding for organ transplantation hold that it is unfair to single out patients with end-stage organ failure who need transplants to bear the brunt of cost-containment efforts; such efforts should be distributed equitably across health care (Task Force 1986).

A second argument for eliminating ability to pay as a criterion for admission to waiting lists focuses on the uniqueness of organ transplantation, particularly because of the social practice of organ procurement and donation. This argument thus identifies another important moral connection between organ procurement/donation and organ distribution (Task Force 1986; Childress 1987). In its efforts to increase the supply of organs, society requests donations of organs from all its segments—for example, through presidential appeals for organ donations. However, it is unfair and even exploitative for society to ask people, rich and poor alike, to donate organs if access to donated organs will be determined by ability to pay rather than by medical need, probability of success, and time on the waiting list. Opposition to commercialization in organ procurement may also support opposition to commercialization in organ distribution. And it is difficult to distinguish buying an organ for transplantation from buying an organ transplantation procedure that includes an organ. This principled argument converges with legitimate worries about the impact of unequal access (based on inability to pay) on the system of organ procurement and donation. As I noted earlier, attitudes of distrust toward the system, including policies of access and distribution, may limit organ donations. Thus, it is not surprising that after Oregon's decision to stop providing Medicaid funds for most organ transplants, "a boycott of organ donations was organized by some low-income people" (Welch and Larson 1988).

Conclusion

There is considerable debate about appropriate policies of organ procurement and distribution, not only because of different interpretations of the facts (e.g., how significant HLA tissue matching is for the success of kidney transplants now that cyclosporine is available), but also because of different interpretations of the meanings and weights of the moral principles that are already embedded in our social institutions, policies, and practices. I have provided an ethical analysis and assessment of various actual and proposed policies of organ procurement and distribution through several major embedded principles, particularly beneficence, nonmaleficence, utility, respect for persons, and justice. While focusing on ethical assessment in terms of acceptability and preferability, I also considered political feasibility, especially in light of public attitudes.

These ethical principles justify the recognition of certain property rights by certain rights holders in relation to different HBPs. For example, I argued for some limited property rights in HBPs by individuals and their families. Assuming the legitimacy of the societal goal of increasing the supply of organs for transplantation, I analyzed and assessed different modes of acquisition or transfer of HBPs: donation (express and presumed), sale, abandonment, and expropriation. In general, for solid organs, I argued for laws and policies to maintain and facilitate express donation of organs by individuals and their families. Such laws and policies, including required request, should be given adequate time to determine their effectiveness before moving to other major alternatives, such as presumed donation and sales. Presumed donation is not ethically unacceptable in principle, but for it to be ethically acceptable in practice, vigorous educational efforts would be required in order to ensure that a person's silence reflects a decision to donate rather than a lack of understanding. Such educational efforts could significantly increase express donation, especially by family members. Similarly, sales of HBPs are not inherently unethical. However, because sales would drive out some donations, would be costly, and could adversely affect attitudes toward the human body through commodification, it is ethically and politically unwise to resort to sales of solid organs until recent and proposed policies to enhance express donation by individuals and family members have had sufficient time to work. Neither abandonment nor expropriation has a significant or ethically defensible role in the acquisition of solid organs, at least at this time.

Regarding policies of allocation and distribution of donated organs, I argued that the community should be viewed as the owner of donated organs and that the public should be heavily involved in the formation of policies of allocation and distribution. Focusing on procedural and substantive policies being developed by UNOS, the national OPTN, in light of the report of the federal Task Force on Organ Transplantation (1986), I examined the point system for cadaveric kidneys, the access of foreign nationals to organs donated in the United States, and the shifting policy regarding multiple listings, indicating how alternative policies reflect alternative interpretations of the meanings and weights of different ethical principles. Finally, I identified two major problems of equitable access to donated organs that cannot be addressed by UNOS: access to the waiting list for donated organs and the role of ability to pay, especially for extrarenal transplants. Throughout I emphasized not only an ethical assessment of organ procurement and organ distribution but also the moral connections between them, as reflected, for example, in the way the public's willingness to donate organs appears to presuppose trust in the system of distribution (e.g., that organs are distributed fairly) as well as trust in the system of procurement (e.g., that patients will not be declared dead prematurely in order to benefit others).

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Is There a Rationale for Regionalizing Organ Transplantation Services?

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Abstract. This paper explores issues in the designation of centers to provide organ transplantation procedures and aftercare, a decision faced increasingly by policymakers, planners, and payers. As background for consideration of the regionalization of organ transplantation services, an array of models of regionalization of health services, ranging from full-scale vertical integration to market-enhancing information provision, is described. In the United States, regionalization has mainly followed the designation model within the certificate-of-need system; vertical integration has been adopted only in limited ways. Next, the authors' review of current approaches to the regionalization of organ transplantation centers by public and private payers indicates that designation of centers is increasing, although the empirical evidence concerning the classes of hospitals upon which designation decisions rest is weak. The authors then review the literature on the relationship between volumes and outcomes on surgical services with particular reference to organ transplantation, which on the whole suggests that a relationship between volumes and outcomes exists. Original empirical analysis of data on kidney transplants that were secured from the Health Care Financing Administration is then presented. The study of the effects of hospital and surgeon volumes on graft and patient survival and of the effect of volume on charges found no systematic influence of hospital or surgeon volumes on graft or patient survival. Some evidence that charges are lower for larger centers was found. The authors conclude that the evidence implies that using volume as the provider characteristic upon which to base designation of transplantation centers is problematic, at least for kidney transplants. Steps policymakers might take to ensure quality of transplantation services is discussed in the final section.

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Introduction

Alternative models. One of the major decisions to be faced by public policymakers, planners, and private payers is designation of the providers to perform transplant procedures and posttransplant aftercare. There are a number of alternative models. One is to take a passive role and leave the decision as to the site of care up to patients and health care providers with no guidance from any third-party source. Buyers and sellers make choices on this basis in the vast majority of markets, and despite the rhetoric from the provider community, in most cases in the health care arena patients and providers have considerable latitude in whom they seek for treatment and in whom they treat, respectively.

Another alternative is a unitary model in which financing and provision are fully integrated. Decisions about the location of delivery sites and levels of care delivered at those sites would be made centrally. The network of care sites would be vertically integrated—that is, there would be explicit delivery mechanisms for identifying candidates for transplantation; for providing medical, social, and psychological services to patients at the pretransplant stage; and for providing the surgical procedure and posttransplant follow-up at the hospital as well as posttransplant follow-up services after discharge. Further, the organ supply and transplant delivery systems would be explicitly linked. Providers of a particular transplant service within a geographic or "catchment" area would not compete with one another for organs or to provide transplantation services. Patients would retain the ultimate decisionmaking power about whether or not to follow the provider's recommendation to have the transplant procedure, but would have no choice of provider. Kidney transplantation is an anomaly in the American context in that universal coverage for the surgical procedure and associated services is available from one payment source, Medicare. Thus, a precondition for the unitary model existed. For various historical reasons, however, the unitary model has not been adopted, at least up to now.

Under a variant of the unitary model, hospitals performing transplants in an area would agree to cooperate rather than to compete. The rationale for cartel-like arrangements is that competition among facilities for scarce organs is not desirable, and newcomers to the transplant field require advice and counsel from the more established centers in the area. The cartel model focuses on the transplant procedures, and, like the unitary model, is horizontal rather than vertical.

There are a number of "mixed" models between the laissez-faire market model (Blumstein and Sloan 1981) and the unitary and cartel models. One model would designate the centers permitted to perform transplant procedures (hereafter called the "designation model"). Designation may be made by a central planning authority, such as a certificate-of-need agency. Under a unitary designation model of this type, all patients, irrespective of payment source, would be limited to particular treatment sites; but, in contrast to the cartel model, transplant centers in an area would compete for organs and patients.

Alternatively, under a pluralistic designation model, each payer would make explicit decisions about treatment sites, thus assuming the role of purchasing agent for the insured and/or taxpayers. The public sector would only be involved in making allocative decisions about treatment sites in its role as third-party payer. In the case of kidney transplantation, it happens that the two designation models collapse into one, since there is a single payer.

Under either designation model, the designator would establish prespecified criteria for site selection. There might also be latitude for subjective expert judgments based on site visits and other data. In both models, the centers at which transplant procedures are performed would have responsibility for arranging for pretransplant and posttransplant care, but in the pluralistic model, provision of care at various levels would not be vertically integrated by catchment area into a single network of facilities. Relationships between community-based providers and the facilities performing transplants would be looser and less formal.

There is a sixth model which is not mutually exclusive of the others—the "information provision" model. Under this model, a public sector agency and/or not-for-profit agency (such as the Consumers' Union) would gather and disseminate information about the quality, availability, and cost of care at various sites. Given the public-good nature of information collection and dissemination, a strong case can be made that profit-seeking organizations would undersupply such services. Further, since transplantation is an infrequently consumed procedure, patients and their community doctors may have inadequate information about the alternatives and find searching for such information on their own to be costly.

Armed with information provided by a public or a quasi-public agency, patients could potentially make better judgments under a laissez-faire market system (Blumstein and Sloan 1981). Good information is integral to the efficient workings of any market system. Alternatively, site designators could use such information to choose among treatment sites. Since the designators would only rarely be expert in transplantation, the information provision model would reduce their search costs as well. Under the unitary model, there would presumably or ideally be an internal system for monitoring the performance of the network and for making corrections as needed.

Evolution of the concept of regionalization. The concept of regionalized health care services evolved in part from the war experience, when casualties were sorted out according to the severity and nature of their injuries and given care as appropriate, either at the front or at base hospitals located away from the front (Pearson 1976: 4). These ideas were formalized in the British Report of the Consultative Council on Medical and Allied Services (also known as the Dawson Report), which was presented to Parliament in 1920 (although it was not really implemented in the United Kingdom until the National Health Service was founded after World War II).

The Dawson Report (and others, e.g., Committee on the Costs of Medical Care 1932 and Mountin et al. 1945) specified a vertically integrated delivery system in which preventive and curative medical services for a well-defined population were structured pyramidally, extending from a base of primary health centers to secondary health centers to teaching hospitals at the top. The system established referral patterns and provisions for transportation (i.e., ambulance service) upward from general to specialized levels of care and established consultation and educational services downward from specialized to general levels. Each facility and practitioner was assigned a specific set of responsibilities. Obviously, regional planning was vital to implementing the system.

Extensions of this early work have developed two distinct models of regionalization (Pearson 1976: 44). The first combined planning, payment, and provision of vertically integrated services for a region within a single agency. The second emphasized voluntary coordination and cooperation among facilities, with a focus on hospitals. Cooperation rather than competition was emphasized because competition was seen as leading to duplication and inadequately small hospitals as well as to excess hospital capacity.

In the United States, this second model has become the more popular of the two regionalization models. This becomes evident when the history of health planning legislation is examined. The first relevant piece of legislation was the Hospital Survey and Construction Act (Hill-Burton) of 1946, which, among other things, required states to develop plans for guiding hospital construction within their jurisdictions. To receive federal construction funds, hospitals then had to show that their construction projects were needed and that they fit within their state's regional plan (see, e.g., Yordy 1976: 203).

The Heart Disease, Cancer, and Stroke Amendments of 1965 authorized grants for the establishment of regional medical programs (RMPs), which were intended to be regional cooperative arrangements among hospitals, medical schools, and research institutions for disseminating current information on advances in the diagnosis and treatment of the act's specified diseases. Because of objections from the private sector, Congress rejected a recommendation of the President's Commission on Heart Disease, Cancer, and Stroke that networks of regional centers, local diagnostic and treatment stations, and medical centers be established by disease category (Yordy 1976: 205), instead authorizing the comprehensive health planning (CHP) program the next year. CHP created a framework for a two-tiered planning system whereby areawide (local) agencies would submit plans for approval and funding to state agencies which were statutorily required to be a part of state government. Many existing agencies wished to maintain their focus on facility planning rather than become "comprehensive" (Sloan and Steinwald 1980: 92).

Two pieces of legislation passed in the early 1970s represented a substantial departure from the earlier comprehensive view of regionalization, which had as its motives promoting access to personal health care services as well as facilitating

the flow of information among providers at various levels of care. In contrast, the motive for the planning provisions in the Social Security Act amendments of 1972[1] and the National Health Planning and Resources Development Act of 1974[2] was clearly cost containment. While coordination was still seen as desirable, the emphasis was on constraining hospital capacity and on consolidating hospital-based services rather than on promoting access. Unlike the vertical coordination that existed in the original concept of regionalization, coordination began to be considered as exclusively horizontal. For example, two neighboring community hospitals would be encouraged to share a CT scanner (see, e.g., Stern et al. 1984). Except for the capital cost provisions for hospitals provided by Medicare and Medicaid, capital financing dollars were totally divorced from health planning. The object of the process was to refuse to fund "unnecessary" expense rather than to facilitate the provision of care to underserved populations. The legislation also focused on institutional inpatient care and excluded ambulatory care.

To be able to refuse funding, the certificate-of-need agencies (which Pub. L. No. 93-641 required states to establish) needed explicit numerical standards. Otherwise, the agencies would have no "objective" grounds for rejecting an application for facilities expansion from an individual hospital or nursing home. The National Guidelines for Health Planning published in 1978 by the U.S. Department of Health, Education, and Welfare provided such standards for bed supply, obstetrical services, neonatal special care units, pediatric services, open heart surgery, cardiac catheterization unit services, radiation therapy, CT scanners, and ESRD facilities. The only remnants of the original concept of regionalization in the guidelines were in the distinctions made between level I, II, and III obstetrical services and neonatal special care units (and even there, the stated objective was to deny "unworthy" applications rather than to facilitate access to such services). Minimum volume and occupancy standards were applied to each service. Justification for these standards was clearly stated in the guidelines:

> Cost savings may be achieved without sacrificing the quality of or access to care through more efficient utilization of existing resources and increased emphases on ambulatory and community services. Moreover, limitations of certain resources, such as open heart units, can lead to improvements in the quality of care while at the same time containing costs (U.S. DHEW 1978: 13040).

The guidelines were by no means the first or the only numerical criteria for setting standards. For years prior to their publication, various professional organizations had set criteria about who should perform what procedures and in which facilities they should be performed. Standards had been proposed, for example,

1. Pub. L. No. 92-603.
2. Pub. L. No. 93-641.

for obstetrical units (American College of Obstetricians and Gynecologists 1974), for cardiac surgery programs, and for cardiac catheterizations (Engle 1971; American Academy of Pediatrics 1978; Ritter 1974; Scannel 1975). As in the guidelines, the basis for these recommendations appears to be professional judgment rather than in-depth statistical analysis of the relationship of quality and/or cost to the proposed standard.

By the late 1970s, the term *regionalization* had become clearly identified with the unitary form of the designation model. In their introduction to an empirical study of the relationship between the number of surgical operations performed at a hospital and mortality rates, Luft, Bunker, and Enthoven (1979: 1364) noted that "the experience hypothesis—if true—would have important implications for the organization of medical care: optimal quality as well as cost savings from economies of scale and experience could potentially be realized through 'regionalization.'" The implication was that by designating the facilities that were permitted to perform certain procedures, it would be possible to simultaneously raise quality and save money. Geographic access was put on the back burner.

The 1980s have seen the demise of a federal role in health planning, a major change in methods used for paying for hospital care, and a more active stance on the part of the federal government in quality assurance, as exemplified by the introduction of peer review organizations (PROs) and the publication of hospital-specific mortality rates. Accompanying these changes has been a change in rhetoric from planning, cooperation, coordination, and regionalization to pluralism and competition. Interest in numerical standards continues, but more from the standpoint of how information on numbers might be used by a patient or a payer to make explicit choices among providers.

The American experience to date with regionalization as a vertically integrated system (as conceptualized in the Dawson Report and other early writings) is extremely limited. The few exceptions include perinatal care and neonatal care (Budetti et al. 1981; Eden et al. 1987; Houck 1978; Merkatz and Johnson 1976; Meyer 1980; Ryan 1975; Walker et al. 1985), trauma care (Colombani et al. 1985; Eggold 1983; Haller and Shorter 1982; Holmes and Reyes 1984; Jackson and Balasubramaniam 1981; Teufel and Trunkey 1977; West et al. 1983), and poison control (McIntire and Angle 1983; Temple 1977; Thompson et al. 1983).

That regionalization could develop in these fields and not in others is understandable. The fields for which regionalization has been more common deal with emergencies. Treatment for emergencies often requires that specialized knowledge be provided quickly. In such situations, it is often not possible for the patient to locate his or her usual provider. In addition, emergency services are not well reimbursed by insurance. But for the vast majority of services, physicians have resisted the notion of external control (Starr 1982) that a formal network is likely to imply. Except in rare situations, such as in the mining industry (ibid.: 315–20), payers have not lobbied for regional networks. Health maintenance organizations provide networking, but not for a specific geographic or catchment area.

The problems that the proponents of regionalized care addressed—inadequate access, poor information on the part of health care professionals at the grassroots level, cost, and quality of care—are real. There is considerably more room for debate about how these problems can best be addressed.

Motivations for the regionalization of transplant services. Transplantation shares with other health care services many of the same problems of access, cost, and quality. Although not documented, there probably are appreciable differences in patient access by geographic area. Public pleas for scarce organs as well as individual fundraising by members of afflicted families heighten concern about equitable access to a scarce national resource. Racial differences have been documented for use of kidney transplants, despite the fact that almost all persons with ESRD are covered by Medicare (Held et al. 1988). Given the high cost of these procedures and the fact that transplants benefit relatively few people, cost is clearly a consideration. Quality of care is also an important issue. Differences in graft and patient survival have been documented. Scarcity of organs induces concern that the better providers use the scarce organs for fear that the less-qualified providers will waste the organs.

However, there are also major differences between transplantation and other technologies. First, with the exception of kidney transplantation, the technology is new and developing very rapidly. Second, the number of operations is constrained by the supply of organs. Thus, at least presently, any burden of constraining the number of operations would not be placed on the delivery system. There is an issue as to how best to limit the rate of growth in the cost per case. Third, the allowable delay between the time an organ is removed and transplanted is limited. For kidneys, the delay ("ischemia" time) may be up to 72 hours, but for hearts the maximum delay is only a few hours (Kaye 1987: 5).[3] A short delay rules out certain remote locations for transplant surgery, at least with today's technology. Fourth, unlike the vast majority of surgical procedures, most of the cost, as well as much of the risk of failure, occurs after the patient is discharged from the hospital. To date, comparatively little thought has been given to the postdischarge transplant delivery system. Finally, the zeitgeist of the late 1980s and early 1990s is far different from that of the 1920s, 1940s, 1960s, and 1970s. Quality monitoring is likely to involve much more frank and open discussion about outcomes than about structure (e.g., staffing ratios) and process (e.g., quality of chart review) than before. There is likely to be more emphasis on pluralism, including selective contracting (with each payer deciding on its own payment policy), and less emphasis on public planning. Competition is likely to be favored over provision by vertically integrated monopolies.

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3. See also testimony of Roger W. Evans before the Subcommittee on Health and the Environment, 29 July 1983. Graft survival of kidneys is better if the delay is shorter; see Iguro et al. (1985: 169–74) and Takiff et al. (1986).

Methods of regionalizing transplant centers

The payers and regulatory agencies involved. Each of the major payers and regulatory agencies has addressed the question of the regionalization of transplant services. Medicare, state Medicaid programs, Blue Cross and Blue Shield, commercial insurance companies, the United Network for Organ Sharing (UNOS)—the national transplantation network, and state certificate-of-need (CON) programs have dealt with establishing criteria for limiting provision of transplantation services to certain centers. Beginning with efforts to regionalize ESRD programs in the late 1960s, various models of regionalization have been applied to transplantation services, including designation, horizontal integration through coalitions (consortia), and vertical integration via networks.

Following are descriptions of approaches to regionalization of transplantation services and the standards used by various payers and regulatory organizations. We review in turn the approaches used by Medicare for kidney and heart transplantation, UNOS membership standards, state criteria (including Medicaid, CON, and consortia), and standards of private third-party payers, with reference to the influential recommendations of the national Task Force on Organ Transplantation (1986). In the course of the review, we address the following questions: What are the pressures to adopt various models of regionalization? On the basis of what empirical evidence, if any, have arguments for the various regionalization models as applied to transplantation been based? To what extent is there a unitary (government-designed) model and to what extent are private payers doing their own regulating? What has been the success or failure of the various models in the transplant field?

Medicare criteria. *Kidney transplantation.* An understanding of the regionalization of kidney transplantation centers is central to a consideration of criteria for other transplant services because of the relatively lengthy experience with programs for renal transplantation. Furthermore, the Medicare program is important because it establishes precedents for other governmental and private payers—not only in regard to reimbursement policy, but also in terms of professional standards, including criteria for center designation. As discussed earlier, a condition existed for establishing a vertically integrated regionalized system for the Medicare ESRD program because there was a single governmental payer. However, this model was not adopted, and the model finally put in place was more limited.

ESRD program regulations issued in 1976 required that Medicare reimbursement be tied to membership in ESRD networks, which were based on rationales of access, quality, and efficiency:

> The broad array of professional skills and facilities involved in the treatment of persons with ESRD indicates the need for a system to promote effective coordination. . . . During the past decade, programs conducted by agencies

> of the Public Health Service have demonstrated that integration of hospitals and other health facilities into organized networks is the most effective way to deliver ESRD care. An organized network tends to assure coordinated patient referral as well as access to resources. It also permits the concentration of equipment and specially trained personnel in centers where they can be used efficiently to treat large numbers of patients (Social Security Administration 1976: 22502).
>
> Network areas are designated for the purpose of geographically describing the location of groups of ESRD facilities which share a collective responsibility to provide access to the various levels and treatment modalities of ESRD care (ibid.: 22513).

Services in each network were to include organ procurement agencies, dialysis centers, and transplant centers, and staffing requirements for these services were specified. The 32 network catchment areas, each of which was to include two transplant centers where possible, were based on existing referral patterns and on minimum populations (3.5 million for all but six areas). Each network would be governed by a network coordinating council with representation from all ESRD facilities in the network. Networks were to establish medical review boards to review the appropriateness of patient care and collect data for a medical information system.

The networks were given local authority to define their functions within the broad parameters stated in the federal regulations. The regulations only specified that the networks and their councils were to act as liaisons between the federal government and available community resources. In response to comments on the proposed regulations that the definition of network functions should be more specific, the Department of Health, Education, and Welfare replied that the regulations provided the flexibility necessary for networks to meet the needs of their specific regions. The networks remained local or regional, in contrast to the national network that federal law later mandated in 1984. (See the discussion of the UNOS network below.)

The transition from design to actual implementation of the ESRD networks was filled with controversy. Friction arose over the geographic boundaries and populations of catchment areas, the definition of patient referral patterns in areas such as multistate SMSAs, the organization of large urban areas with several major medical centers, the relationship—or lack of one—of networks to HSA and PSRO areas, the functions of networks, and the financing of Medicare copayments for patients in multistate networks. Many of the problems in implementing the regionalized ESRD network concept were similar to those that arose in response to the National Health Planning and Resources Act of 1974 (Sloan 1988). Proven regionalization models and adequate data that could be used as the basis for network design were lacking. In spite of assertions by planners, there was little actual documentation for the need for governmentally mandated coordination among institutions providing ESRD services (Rettig and Marks 1981: 190).

Volume criteria for the ESRD program were also mandated in a brief section of the massive Social Security bill that was passed in October 1972. The bill laid down conditions for Medicare reimbursement of renal services, authorizing DHHS to reimburse for kidney transplant and dialysis procedures only those treatment centers meeting DHHS standards, which were required to include a minimal utilization rate and a medical review board for screening patients. The final regulations, published after four years of study and argument, established as criteria for Medicare reimbursement minimum utilization rates of 15 or more transplants performed annually for institutions with unconditional status and 7–14 for institutions with conditional status in order to assure quality of care and lower cost by concentrating procedures in fewer centers.

That there was little or no empirical basis for the rates is reflected in the department's response to comments challenging the proposed standards:

> A major comment was that there should be no minimum utilization rates because evidence is lacking that the number of procedures performed correlates either with quality improvement or cost efficiency. Although it is true that there is a lack of conclusive evidence which establishes with certainty a relationship between utilization rates and the efficiency and effectiveness of care, it can be rationally assumed that such a relationship does exist and thus requirements for meeting minimum rates. As required by law, minimum utilization rates have been retained (Social Security Administration 1976: 22507).

The final utilization rates for unconditional approval resulted from a four-year process of ratcheting the number downward from 50 transplants per year (in 1973 discussions) to 25 per year (in the 1975 proposed regulations) to 15 per year (in the 1975 final rule) (Rettig and Marks 1981: 230). In fact, the minimum standards were never implemented (Task Force on Organ Transplantation 1986: 110) in the face of court challenges from providers who were refused certification.[4]

The gradual erosion of the ESRD minimum volume standards may hold lessons for subsequent attempts to establish standards for transplantation services. As Rettig and Marks (1981: 230) observed, the basis for the ESRD standards was the opinions of medical experts, which supported the ideological preferences of government planners, rather than empirical evidence and analysis. Such criteria are unlikely to withstand pressures from excluded providers and other disgruntled political interests.

In 1978, the 1976 Medicare ESRD regulations were incorporated without modification in the newly promulgated guidelines for the national health planning system concerning the "supply, distribution and organization of health resources" (U.S. DHEW 1978: 13045). The ESRD network and volume criteria are consonant

4. Personal communication with Eugene Pierce, 24 May 1988.

with the approach of the health planning guidelines that established national standards for minimum volume and/or bed size of several high-cost medical and surgical services and for the organization of obstetrical and neonatal services into regionalized networks that linked facilities providing three levels of specialization. However, the ESRD minimum volume guidelines differ from most of the health planning volume guidelines in that ESRD guidelines are for specific procedures rather than for facilities (Evans and Broida 1985: 39-3).

Heart transplantation. In 1987, the agency responsible for the administration of Medicare and Medicaid, the Health Care Financing Administration (HCFA), extended Medicare coverage to heart transplantations (HCFA 1987). The decisionmaking process leading to HCFA's decision to cover heart transplants began with events eight years earlier, when HCFA decided to cover the procedures only at Stanford University Medical Center in 1979, rescinded the decision in 1980, and initiated the National Heart Transplantation Study in order to determine the efficacy of heart transplantation (Evans and Broida 1985: ES-6).

The model of regionalization adopted by HCFA is center designation. HCFA's coverage of heart transplantation is limited to procedures performed in centers that meet three types of criteria: professional requirements, including composition of the transplant team, professional qualifications and experience, laboratory standards, and treatment protocols; volume criteria, specifically that centers must have performed at least 12 transplants per year for the past two years and 12 transplants in the previous time period after 1982; and outcome criteria, for which centers must show actuarial survival rates of 73 percent of patients one year after transplantation and 63 percent after two years (HCFA 1987: 10947). HCFA's stated rationale for the designation of centers was "not to restrict competition but to maintain the quality of services required by this complex procedure, provide coverage of the benefit at facilities and under conditions that have been shown to be safe and effective, and allow entry of new, qualified providers" (ibid.: 10937).

In the interest of designating the most technically qualified centers, HCFA declined to base center designation on criteria to achieve the goal of geographic access, in spite of objections that "in various areas of the country, travel distances present problems of time and expense, not only for the patient and family members, but for the organs being transplanted" (ibid.: 10943), since viability of transplanted cardiac allografts is related to the duration of ischemia and function may be severely impaired when ischemia exceeds several hours. Furthermore, HCFA rejected arguments that regional centers could lessen competition for donor organs and make patient care easier and less costly (Renlund et al. 1987: 874). Little attention was given in the regulations to the extensive, lifelong medical supervision required by cardiac transplant patients (see Vanderbilt University Medical Center 1987). The agency also declined to consider joint applications from groups of providers (or "consortia") (HCFA 1987: 10943) and placed no limit on the number of centers that could receive approval. HCFA's emphasis on technical quality was

emphasized by a HCFA official, who stated, "HCFA's job is not to worry about followup and access issues. We are simply concerned about payment for quality procedures. The odds of the patient's surviving are our only consideration."[5]

The regulations echo views expressed in both the National Heart Transplantation Study (Evans and Broida 1985) and the report of the Task Force on Organ Transplantation (1986), which Congress created in 1984 to make policy recommendations on a broad range of transplantation issues. The National Heart Transplantation Study voiced the concern that Medicare coverage of transplantation might cause the number of heart transplantation programs to be excessive, thus constraining the number of procedures performed per year by any one center to an unacceptable level (Evans and Broida 1985: 39). The Task Force on Organ Transplantation (1986) also questioned the wisdom of allowing the number of centers to increase, since further diffusing the scarce organ supply could make it difficult for established centers to conduct clinical trials or maintain cost-effective transplantation teams and resources.

The basis of the "optimal level" of procedures suggested by the National Heart Transplantation Study was derived from the response of heart transplant centers to a single survey question, "How many heart transplants would you like to see your institution perform each year?" The responses, which ranged from 5 to 45 procedures, was averaged to derive an optimal number of 20.6 (Evans and Broida 1985: 39-62, 39-64, and Table 39-34).

HCFA decided against using the study's optimal level and chose instead the task force's recommendation of 12 transplants annually for existing centers (Task Force on Organ Transplantation 1986: 120), while noting that "the criteria [including experience and survival rates] we have proposed may need to be updated periodically to recognize further developments in the technology and procedures for heart transplantations" (HCFA 1987: 10935). The task force had difficulty in reaching agreement on the minimum volume level because of the lack of an empirical basis for assuming a volume/quality or volume/cost relationship (Task Force on Organ Transplantation 1986: 116). The task force finally concluded that it could only use its best professional judgment in determining a minimum volume (ibid.: 120).[6]

HCFA also came up with new survival rate criteria, basing the criteria on "an analysis of available survival data and judgments about what can be reasonably expected" (HCFA 1987: 10941). According to one HCFA official, the Medicare survival standards represented increases (based on improved clinical outcomes) over the National Heart, Blood, and Lung Institute (NHBLI) standards that were established in the early days of the federal government's consideration of the heart

5. Personal communication with Ronald Milhorn, 7 March 1988.

6. On the same basis, the task force also recommended annual volume criteria of 25 for kidney transplants and 15 for liver transplants. The task force estimated that 29 of the 169 kidney transplantation centers in existence in 1985 would be unable to meet the 25-procedure standard (Task Force on Organ Transplantation 1986: 121).

transplant coverage issue;[7] HCFA raised the Medicare survival standards and also added two-year survival to the NHBLI standards, having found that "a real break in survival figures occurred between the eleventh and fifteenth months."[8]

Opponent's of HCFA's criteria suggested that designating centers based on survival rates ignored the importance of patients' quality of life, although they recognized the difficulty of measuring this variable (Renlund et al. 1987: 875). They also argued for raising HCFA's survival rates, since many centers had achieved survival rates of over 80 percent and higher rates need not discourage transplantation of high-risk patients if the patients are selected appropriately (ibid.). Objections to the volume criteria were also raised, especially the contention that experienced persons can establish a successful cardiac program in less time and that some centers obtain experienced persons from other centers (ibid.).

Congress added to HCFA's regulations a further potential constraint on the diffusion of all transplant procedures (including heart transplants) by requiring that hospitals performing transplants be members of the Organ Procurement and Transplantation Network (OPTN) as a condition of receiving Medicare and Medicaid reimbursement for any of the hospitals' services.[9] Thus, the criteria for membership in the UNOS, the private, nonprofit organization selected to implement the national network for organ procurement agencies and transplantation programs, have an impact on transplant facilities that is potentially as powerful as HCFA's criteria for Medicare coverage of transplants.

UNOS criteria. The National Organ Transplant Act[10] required the U.S. Department of Health and Human Services (DHHS) to fund a contract for "a single national network of transplant centers, procurement agencies, and histocompatibility laboratories that would improve the identification of donors, the acquisition of organs, and the matching of donor organs and potential transplant recipients" (U.S. DHHS 1987: 2).

UNOS, which was awarded the contract in 1986, established principles governing allocative decisions made locally, regionally, and nationally (ibid.: 3-ES), based largely on the recommendations of the Task Force on Organ Transplantation (ibid.: 1). UNOS has important functions in relation to both the transplantation process and the organ procurement and distribution process. In the following section, we examine the concept of *network* as it applies to UNOS and UNOS's standards for transplant centers.

The network as prescribed in the relevant statutes and regulations represents an attempt at regionalization that has features of the unitary model that was described

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7. Personal communication with Ronald Milhorn, 7 March 1988.
8. Personal communication with Ronald Milhorn, 7 March 1988. See also Evans and Broida (1985: ES-46).
9. Pub. L. No. 99-509, § 9318.
10. Pub. L. No. 98-507.

earlier in this article. All elements of the system—organ procurement agencies and transplant centers—are required to join the network, and the procurement agencies are designated on the basis of geographic catchment areas. One payer, Medicare, exercises extensive (although not exclusive) influence. However, transplant centers may choose organ procurement organizations (OPOs) outside their regions, and patients may seek care (and listing on the network's computerized organ procurement and distribution list) at more than one center.

The UNOS network. UNOS's authority to establish the network and rules for OPOs derives from the National Organ Transplant Act of 1984, which mandated establishment of a national network, and the Sixth Omnibus Budget Reconciliation Act (SOBRA),[11] which added steps to ensure that procurement agencies do not bypass the system by requiring that OPOs participate in the network as a condition of Medicare and Medicaid participation. SOBRA required further that OPOs be designated by DHHS to procure organs within a specified service area and meet performance standards. OPOs—which are heavily dependent on Medicare and Medicaid funding, since the bulk of their activities involve kidney procurement and distribution—have little choice as to whether to join UNOS and abide by DHHS's designation decisions.

The National Organ Transplant Act of 1984 carries the network structure beyond the local/regional ESRD networks, which, in spite of federal efforts to establish a uniform system, are actually decentralized, purely voluntary, lack criteria for sharing organs, and lack procedures for cross-matching before transporting organs (Prottas 1985: 105). Congress's rationale for establishing a national procurement and distribution system was the low rate of organ procurement relative to the need and potential availability of organs for transplantation, which Congress attributed to "the lack of organization in the nation's procurement efforts," and the finding that "while there is currently a computer system to match potential recipients with donated kidneys, the system is not truly nationwide and does not fully serve the needs of patients who need hearts or livers."[12]

The Task Force on Organ Transplantation (1986) expanded on Congress's rationales for a national system, citing the failure to procure available organs, the wastage of organs, the inequitable distribution of organs, the lack of highly sensitized patients' access to a sufficiently large donor pool to meet their need for organs, the lack of standards among OPOs, and difficulties in tissue typing. Large or medium-sized OPOs were found to be more effective than smaller ones, and competition for organs among OPOs in the same local areas was thought to be "damaging to the organ procurement process" (Task Force 1986: 59). The task force recommended that DHHS regulate OPOs by establishing certification and productivity standards and by certifying OPOs on a regional basis (one OPO per SMSA or existing organ donor referral area, whichever is larger) (ibid.: 5).

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11. Pub. L. No. 99-509.
12. H.R. Rep. No. 98-575, pt. 1, at 18 (1983).

UNOS membership criteria for OPOs consist of protocols (based on the Association of Independent Organ Procurement Agencies criteria) that must be followed in each phase of organ procurement and distribution (UNOS 1987). UNOS makes no rules concerning OPO catchment areas, the number of donated organs that must be acquired and used for transplantation, and coverage of hospitals in the OPO regions.

Although UNOS's process-oriented requirements are likely to have an impact on the development of a national system, SOBRA's approach, implemented in the 1988 regulations, requires regional designation and performance standards that are more far-reaching (HCFA 1988). SOBRA/HCFA sets standards for designating one OPO per geographic area, which is defined as an area having at least 2.5 million population or yielding at least 50 donors per year and including either an entire SMSA or no part of an SMSA (ibid.: 6550). A HCFA-certified OPO must also have working relationships with at least 75 percent of the hospitals within its service area. Numerical performance standards require the procurement of at least 23 cadaveric kidneys annually per one million population, a minimum of 19 cadaveric kidneys procured and transplanted annually, and provision of multiple organs for transplantation from a minimum of 20 percent of the total donors procured annually in the service area.

There has been controversy about the certification of OPOs, just as there has been controversy over UNOS membership and HCFA designation of heart transplant centers. In some regions, OPOs have battled for designation. In the thick of the designation process, Fackelmann (1988) reported:

> OPAs [organ procurement agencies] are in a frenzy trying to gain Medicare designation. Those that wind up entangled in turf wars will have to bring their cases to Washington for a HCFA ruling that makes sense for patients and transplant centers. And there is no guarantee that—once all these precincts and approved agencies have been named—there will be a significant increase in the nation's organ supply.

The difficulty of regulation by designation is indicated by the fact that some of the 73 approved OPOs cover overlapping regions (AHA News 1988: 8).

Transplant centers. As noted above, Congress subsequently required hospitals with transplant centers to join the network as a condition for receiving Medicare and Medicaid coverage for all services, not just transplantation.[13] UNOS, like Medicare, uses the designation model of regionalization for transplant centers. Criteria for transplant centers deal mainly with staffing (including the composition of the transplant team and the professional training and experience of transplant surgeons and physicians) and with facility requirements and medical protocols; there are volume criteria only for transplant training centers. Transplant centers must also

13. Pub. L. No. 99-509, § 1138(a) (1986).

report survival information for grafts and patients. Centers with survival rates in the lowest 5 percent of the distribution of survival rates of all UNOS members will be subject to scrutiny of the quality of their programs and considered for probation if case mix or similar circumstances fail to explain the poor outcomes (UNOS 1987: B-5). UNOS's interest is in assuring the quality of transplantation services rather than in encouraging the existence of a particular number of transplant centers or in restricting entry.[14]

UNOS has been considering the establishment of more stringent criteria for heart transplant programs—including minimum volumes (12 per year) and survival rates (73 percent after one year, 65 percent after two years)—as a condition of ongoing (not initial) UNOS membership.[15] Heart transplant programs that fall below the volume and survival rates would be scrutinized for quality and would eventually lose membership if adequate explanation for the failures or improvement in meeting the criteria were not forthcoming. Pressure for the more stringent standards has come from "the heart transplant community, which is more enamored of numbers than the renal specialist community."[16]

Controversy concerning criteria for transplant centers erupted with the 1986 passage of the requirement of UNOS membership for hospitals that perform transplants as a prerequisite for Medicare and Medicaid coverage.[17] Heart transplant centers had particular difficulty in qualifying for UNOS membership (Fackelmann 1988). The major stumbling block was UNOS's stricter criteria for transplant surgeons' training; UNOS required three years of experience or one year of post-residency training plus one year of experience, compared to Medicare's requirement of one year of training or one year of experience (HCFA 1988: 6530). Negotiations between HCFA and UNOS resulted in UNOS's offering provisional membership to centers that could not meet the requirements for full membership and establishing a conflict resolution process (ibid.: 6528–30).

States' criteria. All but 20 states limit extrarenal transplants to designated centers, according to the most recent systematic survey (Zachary 1986).[18] Our informal survey of several states and review of the literature indicate that states continue to seek ways to control the diffusion of transplant technology (and their payment obligations) by designating centers. States use a mix of approaches to regionalization, frequently in combination, including designation for Medicaid reimbursement, certificate-of-need programs, and horizontal arrangements (consortia) among providers (Lindsay and McGlynn 1988: 898). The rigor of state regulation is highly variable, as indicated in the following discussion.

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14. Personal communication with Eugene Pierce, 24 May 1988.
15. Personal communication with Eugene Pierce, 24 May 1988.
16. Personal communication with Eugene Pierce, 24 May 1988.
17. Pub. L. No. 99-509 (1986).
18. The Intergovernmental Health Policy Project is in the process of surveying states about their coverage of transplants, including their approaches to center designation. By the time of this printing, the survey results should be available. (Personal communication with Richard Merrit, 2 May 1988.)

Medicaid. Medicaid coverage of transplants is at the states' discretion. Most states provide coverage of at least some types of extrarenal transplants (Oregon is a recent and notable exception—see Egan 1988), and many states limit Medicaid reimbursement to designated centers, using criteria concerning professional staffing, minimum volumes, and outcomes and frequently following HCFA's lead. Many states favor in-state facilities for Medicaid reimbursement. Some states have reported experiencing pressure from hospitals to weaken or to strengthen their designation criteria, depending on the hospitals' interests. A few examples of state Medicaid designation policies follow.

Iowa's Organ Transplant Task Force recommended the designation of heart and liver transplant centers according to "experience" criteria (Iowa Department of Human Services 1984: 19). The final regulations specified volume criteria of 12 procedures per year; however, the regulations were weakened by allowing conditional Medicaid coverage for centers not meeting the volume criteria (Iowa Organ and Tissue Transplant Commission 1988: 12) so that Iowa hospitals could qualify, thereby "enabling Iowa Medicaid money to stay in Iowa." The designation process in Iowa has been weakened further by the state legislature's rescission of the Organ and Tissue Transplant Commission in mid-1987.[19]

Missouri's state Medicaid plan designates transplant centers according to process criteria (staffing, protocols, and the provision of a full range of services); there are no volume criteria, but centers must indicate a commitment to evaluation based on costs and outcomes (Missouri Division of Medical Services 1986: 792–93). The regulations represent a compromise between the interests of transplant physicians at the academic medical centers, who pressed for designation, and physicians at nonteaching hospitals, who resisted it.[20]

The state Medicaid plan in Illinois designates centers for extrarenal transplants according to the usual process criteria and minimum volumes of six transplants per year (Illinois Department of Public Health 1988b) in order "to assure that our money goes into established programs and isn't used for start-up."[21] Data on survival is collected but is not yet used for center designation.[22] In-state and out-of-state hospitals both currently receive designation (Illinois Department of Public Health 1988a: 6).

California's Medi-Cal program designates in-state facilities for heart transplants (Stanford) and livers (UCLA and UC–Davis) (Zachary 1986). Maryland designates Johns Hopkins, the University of Pittsburgh, and the Medical College of Virginia for various extrarenal transplants (Fackelmann 1985: 67).

Certificate-of-need programs and transplant consortia. Most states have had certificate-of-need (CON) programs to control facility development and state ob-

19. Personal communication with Barbara Momberg, 27 May 1988.
20. Personal communication with Helen Clarkston, 26 May 1988.
21. Personal communication with Jeanne Cronister, 24 May 1988.
22. Personal communication with Jeanne Cronister, 24 May 1988.

ligation to fund new services (Lindsay and McGlynn 1988: 898). Although a number of states repealed their CON programs upon repeal of the federal health planning law in 1986, others have kept and even strengthened their programs (Fackelmann 1987). Some states have regulated the growth of transplantation programs by using their CON programs, sometimes in combination with designation of consortia (cooperating groups of providers). Under consortium arrangements, hospitals agree to standardized protocols for patient selection, physicians receive staff privileges to do transplantations in all member hospitals, personnel is shared frequently among hospitals for donor and recipient operations, regular meetings are held among physicians in all member hospitals to discuss patients, and a common database is maintained (Jenkins 1986; Russell 1986).

Critics point out limitations in CON and consortia as approaches to restricting the development of transplantation services. CON frequently fails to apply to transplant programs because the capital expense is less for transplantation than for some other high-technology procedures; the main expense is for adding staff rather than for facility expansion (Employee Benefits Research Institute 1984: 5; Fackelmann 1985: 4; Russell 1986: 866). Consortia are viewed as "a weak and transparent device to permit more hospitals to enter the field" (Russell 1986: 865) and explicitly as a means of getting around minimum volume criteria (Gore 1987). CON programs and consortium arrangements have adopted process criteria, including minimum volumes, as the following description of several states' activities indicates.

Massachusetts was the first state to establish consortium arrangements to control the proliferation of transplant programs by the numerous hospitals in the state that sought determinations of need (DONs) for their programs in the early 1980s. The state used its strong DON program and the recommendations of a task force on organ transplantation to require that extrarenal transplants be restricted to programs that participate in a "worthwhile" consortium that operates as a single, integrated service (Massachusetts Task Force 1984: 87–96). Transplant hospitals are approved for DONs individually and also must join the consortium. The task force emphasized "a presumption that all currently offered services have a higher priority than organ transplantation" (Annas 1985: 4). Therefore, conditions were established for receipt of DONs that included the applicant's agreement not to reduce free care for nontransplant activities (ibid.). There are no volume or outcome criteria for individual hospitals, although survival rates in each institution are evaluated before unconditional DONs are issued (after three years of conditional approval).[23] Massachusetts currently has two four-hospital consortia, one each for heart and liver transplants, with applications pending from essentially the same hospitals for pancreas and heart/lung programs.[24]

Ohio's consortium arrangement was developed by the Ohio Department of Health (which administers the CON program) in conjunction with three hospitals

23. Personal communication with Joan Gorga, 17 May 1988.
24. Personal communication with Joan Gorga, 17 May 1988.

that intended to apply for CONs for extrarenal transplant services in 1983, after the newly elected governor placed a moratorium on new CONs because of the state budget deficit.[25] Conditions for participation in the consortium include provision of care without regard to patients' ability to pay (to mitigate patients and families having to resort to public pleas for funds); fairness and equity concerning choice of recipients; a common database and collaboration in medical and surgical procedures and in the selection of patients for transplantation; and contribution of 25 percent of surgeons' fees to a "cushion" fund to pay for transplants for patients without coverage.[26] Further, consortium members must be tertiary care centers, must have performed at least 50 renal transplant procedures per year, and must have specified personnel and facilities.[27]

Under threat of antitrust action from a hospital that had been denied membership in the consortium, the CON regulations were revised in 1988 to put distance between the CON program and the consortium.[28] Under the new regulations, CONs are granted to individual hospitals, which in turn apply for membership in the consortium.[29] The new regulations greatly expand the requirements for CONs by establishing volume criteria for heart and liver programs (12 and 10 per year, respectively), by barring approval of new programs until existing programs are performing at specified combined volumes (120 heart and 80 liver transplants per year), and by establishing population-based need standards for transplants.[30] The consortium is currently examining outcome criteria for entry into the consortium and for ongoing peer review.[31]

The Washington (D.C.) Regional Transplant Consortium resulted when six institutions made a joint application for the single CON for heart transplant services allowed under the District's CON program in 1986.[32] Pressure for restricting the development of heart transplant facilities came from private insurance companies[33] as well as from federal policymakers (Gore 1987). Subsequently, the consortium was approved for heart and liver transplants, and as of May 1988 had a CON application pending for heart/lung transplants. Criteria are similar to those for other consortia described above (Washington Regional Transplant Consortium no date).

Maryland's failure to regulate organ transplantation through its strong CON program and creation of a consortium, despite the recommendation of the Maryland Medical Transplant Commission (Maryland Department of Health and Mental

25. Personal communication with Audrey Bohnengel, 23 May 1988. See also Jackson (1985) and Lindsey and McGlynn (1988).
26. Personal communication with Audrey Bohnengel, 23 May 1988.
27. Ohio Certificate of Need Regulations, section 3701-12-33, 1984.
28. Personal communication with Audrey Bohnengel, 23 May 1988.
29. Ohio Certificate of Need Regulations, section 3701-12-33, 1988.
30. *Id.*
31. Personal communication with Audrey Bohnengel, 23 May 1988.
32. Personal communication with Lori Brigham, 24 May 1988.
33. Personal communication with Audrey Bohnengel, 23 May 1988.

Hygiene 1985), is an example of the idiosyncratic development of organ transplantation policy in the states. The commission was created by legislation in 1984 in response to intended development of large transplantation programs at two tertiary care centers, Johns Hopkins and the University of Maryland. Pressure for regulation came from physicians, who were concerned that neither competing program would have volumes sufficient to function, maintain quality, and hold down cost, and from the CON agency, which was concerned that adding expensive transplant programs would raise costs under the state's rate-setting program because other services would have to subsidize transplants.[34] Soon after publication of the commission's report, which recommended CON regulation through a consortium arrangement, the University of Maryland dropped its transplantation program (due to events in its department of surgery that were unrelated to transplantation), leaving Johns Hopkins alone in the transplantation field. Thus, the incentives for designating facilities in Maryland evaporated.

Private third-party payers' criteria. Chronologically, both the Blues and Medicaid preceded Medicare in coverage of transplantations and designation of centers.[35] While the regionalization model used by private third-party payers in the transplantation field has been pluralistic designation to date, private payers have sought federal help in curbing diffusion of these new technologies. Private third-party payers have sought to limit the diffusion of transplantation for reasons of cost and quality, as the Health Insurance Association of America (HIAA), the association representing commercial health insurers, stated:

> Medical researchers have found a high correlation between the frequency with which a given surgical procedure is performed and the success of the outcome. Researchers have also found the reverse to be true: when surgeries are performed infrequently, they are less likely to be successful. Thus, if only a few institutions—centers of excellence—perform a high volume of transplant procedures, the quality of the outcomes is likely to improve, thus minimizing the risk to patients. In addition, this "centers of excellence" approach helps prevent unnecessary duplication of investment in transplant capacity (HIAA 1985: 8).

HIAA and the Blue Cross and Blue Shield Association (BCBSA) pressed for inclusion in the 1984 federal legislation of the "centers of excellence" provision that was included in H.R. 4080, which would have given DHHS authority to restrict Medicare payment for transplantations to centers based on such criteria as staffing, prior experience (including volume standards), participation in procure-

34. Personal communication with Joan Salim, 27 May 1988.
35. Personal communication with Ronald Milhorn, 7 March 1988.

ment programs, and patient selection protocols.[36] The provision, which was called "the most controversial section of the bill" (Iglehart 1984: 866), received mixed reviews from physicians who testified on the provision. The AMA opposed the authority of DHHS to impose restrictions as unwarranted intrusion into medical practice, while several leading transplantation surgeons supported the provision in order to encourage DHHS to lift its ban on coverage of extrarenal transplants (ibid.: 868). The provision was deleted in the final legislation (HIAA 1985: 9; EBRI 1984: 12), although Medicare designation reappeared two years later in modified form in SOBRA, as described above.

The sketchy literature and our informal survey of several private third-party payers indicate that the health insurance industry is wrestling with the issue of center designation. Many plans require that transplants be performed in designated centers as a condition of coverage. Overall, private third-party payers have not invented new rationales or criteria for designation, but rather have marched in step with the other major payers and with the national Task Force on Organ Transplantation.

BCBSA recommends to its members that they use as guides to designation the Medicare policy on heart transplants and the national task force's recommendations, including volume and outcome criteria and provision of a full array of services.[37] Blue Cross and Blue Shield of California was the first plan to limit coverage of transplantations to designated centers (Lindsey and McGlynn 1988: 899), and Blue Cross and Blue Shield of Iowa has followed suit.[38] Metropolitan Life's chief medical director has recommended that the company adopt Medicare criteria in order to assure quality of services, although he judges that designation may increase costs because of added expenses for travel and lodging at distant centers.[39] Equicor faces similar obstacles to establishing criteria, including the difficulty of pricing a service that incorporates the elements of assessment, waiting period, and follow-up.[40] Selective contracting, a natural offshoot of PPOs, is under consideration by many plans.[41] Large companies such as Honeywell that have self-funded health insurance plans are also beginning to designate transplantation centers (Fackelmann 1985: 68). In some states, insurance companies have favored the establishment of consortia as a means of controlling diffusion—for example, Blue Cross and Blue Shield in Massachusetts.[42]

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36. H.R. Rep. No. 98-575, pt. 1, at 18 (1983).

37. Personal communication with Margaret Creditor, 15 April 1988; see also Fackelmann (1985: 67).

38. Personal communication with Marilyn Musser, 24 May 1988; see also Lindsey and McGlynn (1988: 899).

39. Personal communication with Paul Entmacher, 18 May 1988.

40. Personal communication with Eileen Nusbaum, 18 April 1988, and with Robert Zone, 19 April 1988.

41. Personal communication with Joel Miller, 4 May 1988, and Marilyn Musser, 24 May 1988. See also HIAA (1985: 11).

42. Personal communication with Joan Gorga, 17 May 1988.

Empirical evidence on outcomes and cost for designating transplant centers

Outcomes. *Conceptual framework.* A plethora of studies relating patient outcomes to the volume of services provided by hospitals and physicians has appeared during the last decade (Bunker et al. 1982; Flood et al. 1984a, 1984b; Freeland et al. 1987; Hughes et al. 1987; Kelly and Hellinger 1986, 1987; Kempczinski et al. 1986; Luft 1980; Luft et al. 1979; Luft et al. 1987; Maerki et al. 1986; Showstack et al. 1987; Sloan et al. 1986). Other variables, such as hospital bed size, teaching status (Kelly 1988), features of hospital organization (Shortell and LoGerfo 1981), and physician characteristics such as board certification status (Palmer and Reilly 1979; Payne et al. 1984; Strauss et al. 1986), have also been included as determinants of outcomes. The most frequently used measure of outcome is the inpatient mortality rate, defined as the percentage of patients in a diagnostic or procedure category who were discharged dead. Unusually long hospital stays have also been used as an outcome measure, although less frequently. One study (Farber et al. 1981) related frequency of operation to the infection rate for a number of common elective procedures. Another study (Riley and Lubitz 1985) examined survival of Medicare patients within 60 days of surgery. Although the authors have engaged in a considerable amount of curve fitting, only recently have a few studies begun to delve into the reasons for expecting that physicians who perform more procedures and hospitals in which more procedures are performed might achieve better outcomes on average.

For analytical purposes, it is useful to partition the hospitalization process into five phases. First, before admission, physicians may vary in the skill with which they diagnose an illness and in judgments about whether a patient should be admitted to a hospital, when, and for what sets of diagnoses and treatments. Second, there is undoubtedly considerable variation in the skill with which diagnostic and therapeutic procedures that provide the major reason for the patient admission are performed by physicians and other personnel within the hospitals. Some physicians are relatively skilled in surgical procedures. The error rate in some laboratories and radiology departments is likely to be far lower in some hospital facilities than in others. Third, there is the recovery period, either after a major medical event such as an infarction or a surgical procedure. Skill in diagnosis applies throughout the hospital stay as well, since patients' conditions often change and patients exhibit varying signs and symptoms. Health care professionals may differ in their reaction time and in their judgment once they react to an emergency. An inexperienced surgeon may, for example, be less aware of critical points in patient management (Fowles et al. 1987). In some cases, an untoward event may be the result of poor management, such as inadequate infection control. Fourth, the patient's physician decides when to discharge the patient. The fifth phase involves postdischarge management of the patient. This phase is particularly important in the case of transplant procedures.

The main hypothesis in the outcome studies is that "practice makes perfect." Since the vast majority of studies are limited to the hospital stay, they focus on

the second and third phases, at least implicitly. However, decisions made in other phases potentially affect the observed relationships between hospital and physician volume as well. Treatment prior to admission as well as choices made about whether and where to admit affect outcomes after admission. For one, systematically difficult or easy cases may be admitted by high-volume physicians and to high-volume hospitals. An argument that difficult cases are admitted follows from the notion that the more capable providers end up with more complex work. Conversely, these providers may have high volumes just because they are less selective in the cases they admit. The discharge decision makes a difference because earlier discharge increases the probability that a bad outcome will not occur during the stay under scrutiny. The fifth phase, posthospital management of the case, does not directly influence the patient outcome indicators typically used, but it potentially has a major impact on the value of the hospital stay (its cost/benefit ratio).

Understanding the admission selection process is important. First, if high-volume doctors and hospitals treat easier cases, and if complexity of cases cannot be adequately determined from existing data ("unobserved heterogeneity"), then the observed negative relationship between volume and an outcome indicator, such as the inpatient mortality rate, may be spurious, and patients and payers may be worse off with information on volume than without it. Second, several authors have stated that it makes little difference to a patient or a payer whether a high-volume provider achieves a good result through experience with the procedure or case type or whether patients and their personal physicians select the better providers for hospital treatment (see, e.g., Bunker et al. 1982). At any point in time and from a public policy perspective, it makes an appreciable difference whether results improve with experience or whether the physicians and hospitals with bad outcomes continue to perform poorly, even with experience. Providers may persistently perform poorly because of deficiencies in attitude, ability, and/or organization. If, however, providers learn by doing, it may be socially desirable to tolerate some poor outcomes initially. Anticompetitive or franchising effects may eventually follow from permanently excluding inexperienced providers.

Empirical evidence. For the majority of procedures and diagnoses for which results are reported, high-volume hospitals have better outcomes on average. For some, the relationship has mainly been observed at very low volume levels. Linkages between the volume of services and outcomes have been observed for diagnoses/procedures. However, although many volume parameter estimates attain statistical significance at conventional levels, the explanatory power of the volume itself is low. This means that just knowing volume has little explanatory power in predicting a hospital's mortality rate. While the high-volume hospitals achieve better outcomes on average, many low-volume hospitals do well and many high-volume hospitals do poorly. There is empirical evidence that procedure-specific mortality rates decline over time, implying that experience matters. Hospitals that stopped performing a procedure, however, did not have unusually high mortality rates before they quit (Sloan et al. 1986).

A study of coronary artery disease outcomes at a single hospital (Hemenway et al. 1986) revealed an improvement over time in quality of outcome, as measured by substantial symptomatic improvement in the first-year follow-up examination as compared to the patient's status at the entry point into the study. Although the sample sizes were small, there was some indication that the moderately ill patients were the prime beneficiaries of providers "learning by doing."

The estimated effect of hospital volume on inpatient mortality varied among the diagnosis/procedure categories in studies investigating this relationship, for reasons not easily understood. In some cases, the negative influence of volume tapered off at low volume levels, but for many categories, the volume associated with minimum mortality was far beyond the volume levels of the vast majority of hospitals (Sloan et al. 1986).

Most of the studies used the mortality rate at discharge as the dependent variable. Using data on Medicare beneficiaries, Riley and Lubitz (1985) assessed the influence of the number of beneficiaries receiving one of eight surgical procedures at a hospital on mortality within 60 days of surgery. They found that high surgical volume was significantly associated with lower mortality for resection of the intestine, coronary bypass surgery, transurethral resection of the prostate, and hip arthroplasty, excluding total hip replacement. But for cholecystectomy, total hip replacement, inguinal hernia repair, and femur fracture reduction, the authors found no linkage between surgical volume and postsurgical mortality. The same analysis was repeated with the inpatient mortality rate as the dependent variable, and the relationships were much stronger. This finding suggests that high-volume hospitals may be capable of carrying ill patients through to discharge, but the gains are to some extent offset by higher death rates soon after such patients leave the hospital.

The mechanisms underlying the observed negative relationship between the volume of cases in specific diagnostic/procedure categories performed at a hospital and patient outcomes are not well understood. The most in-depth study of the patient selection process, which may be responsible for the observed negative relationships, is by Luft et al. (1987). The authors evaluated two alternative hypotheses: the "practice makes perfect" hypothesis (i.e., higher volume reduces the death rate) and the "selective referral pattern" hypothesis (i.e., physicians and hospitals with better outcomes attract more patients). Their results suggested that both hypotheses were partly valid. On selection, the authors found that high-volume hospitals received more transfers from other hospitals and that a smaller fraction of patients was discharged from such hospitals to other hospitals. Based on patient characteristics the authors were able to measure, they computed the probability of inpatient death for each patient in their sample. They found that for several diagnoses and procedures, the expected death rate was higher for low-volume than for high-volume hospitals, suggesting that physicians in high-volume settings avoid certain procedures (such as total hip replacement or cardiac catheterization)

in very high risk patients. An alternative explanation is that many patients with severe medical problems would have gone to high-volume hospitals if they had been able to get to such facilities—that is, if the admission had not been an emergency.

The authors also specified and estimated a two-equation model using volume and the inpatient mortality rate as the two endogenous variables. For two categories (total hip replacement and hysterectomy), the results indicated that both hypotheses had merit. For five categories (acute myocardial infarction, cholecystectomy, stomach operations, intestinal operations, and respiratory distress syndrome), there was greater support for the "practice makes perfect" hypothesis. However, for aneurysm, fracture of femur, ulcer, transurethral prostatectomy, and coronary bypass graft, the evidence supported the "selective referral pattern" hypothesis. The authors concluded that the patient categories exhibiting results consistent with the selective referrals are generally more complex and likely to be referred. Without further documentation, we do not accept this generalization. In fact, taken at face value, these results call into question the minimum volume standards for such procedures as coronary bypass surgery.

Surprisingly, the empirical results on the influence of volume per physician are far weaker than those for volume at the hospital level of aggregation. In most of the studies that gauged the effect of physician volume, the measure used was physician volume for a single hospital rather than for the practice as a whole. An exception is a study by Kempczinski et al. (1986), which examined the influence of surgical caseload on the results of carotid endarterectomy. A total of 750 operations were performed on 656 patients by 61 surgeons (11 operations per surgeon) over a twelve-month period. Although there were differences in postoperative stroke and mortality by surgeon volume (the high-volume surgeons had better results), the differences were not statistically different at conventional levels.

In an analysis of heart disease and hospital deaths, Kelly and Hellinger (1986) found that acute myocardial infarction (AMI) patients were more likely to survive when their attending physicians treated large numbers of AMI patients. However, in a study of inpatient mortality of patients with four conditions for which a surgical procedure was performed (cancer of the stomach, peptic ulcer, cancer of the colon and rectum, and abdominal aneurysm), the number of operations performed by the surgeon at the hospital had no effect on outcome, while hospital volume for the same procedures had a negative influence. In another recent study, Hughes et al. (1987) found that both hospital volume and the fraction of patients operated on by low-volume surgeons influenced outcomes for many of the ten procedures examined. On the whole, the hospital volume variable performed better, judging by the fraction of parameter estimates attaining statistical significance. A notable exception, however, was that low-volume surgeons did relatively well in the case of coronary bypass graft procedures. Such surgeons performed twelve or fewer bypass grafts per year. Selection is again a possibility; that is, the low-volume

cardiac surgeons may have operated on less-ill patients. Results from the several studies that have assessed the influence of physician board certification status and patient outcomes are mixed.

Although the volume of patients treated in various diagnosis/procedure categories most often has suggested that the high-volume hospitals have better outcomes when volume of cases is held constant, large hospitals have often shown worse outcomes. Likewise, teaching hospitals have shown better results in treating some groups of patients and worse results in treating others (see Kelly 1988). Perhaps these results suggest that even the most well known hospitals have weak departments. Even though this argument is somewhat plausible, realistically, many of the factors that potentially influence the hospital pertain to the hospital as a whole—the quality of diagnostic support services (such as radiology and pathology), anesthesiology, nursing, infection control, and medical staff organization, including peer review by members of the hospital's medical staff. Or patient selection could underlie the relationships observed between hospital bed size, teaching status, and mortality.

Kidney transplant outcomes. Most studies of graft and patient survival following a kidney transplant have focused on strictly medical issues, such as the role of the donor/recipient match and the effectiveness of alternative immunosuppressants. A few studies, however, have included facility variables. To our knowledge, the only study to directly assess the effect of the number of kidney transplant operations on patient and graft survival is by Held et al. (1986), in which the authors measured volume with a set of binary variables for the number of transplants performed per year at the center. The parameter estimates on the volume variables were small, and in all cases the standard errors exceeded the parameter estimates.

Several other studies have reported results indicative of "center effects." The authors found center-specific differences in outcome, often holding characteristics of the patient and treatment approach constant. However, in most studies, they could not (or in any case did not) document the reasons for such differences (Benlahrache et al. 1987; Cicciarelli 1985; Gilks et al. 1984; Krakauer 1986; Krakauer et al. 1983; Mickey 1986; Opelz et al. 1975; Sanfilippo et al. 1985).

In an early study, Opelz et al. (1975) found no evidence that one-year graft survival rates of cadaver donor transplants were lower in smaller centers. However, because of the low number of operations, the reported rates for the smaller centers were more often far from the all-center mean. The higher variation for these centers was attributed to random fluctuations. The authors did not account for other factors affecting graft survival.

Krakauer et al. (1983) and Krakauer (1986) assessed the effects of a number of factors on graft and patient survival using a Cox proportional hazards model. Substantial differences in relative risk at various centers remained after controlling for a number of other influences, such as use of cyclosporine, recipient age, race, tissue match, and blood transfusions prior to transplantation. Controlling for fac-

tors relating to patient health and the treatment process reduced differences among the centers. The studies did not indicate the number of transplants performed at each center. Mickey's (1986) analysis of 1983 and 1984 data also found that adjusting for differences in patient mix did not eliminate differences in survival rates by center. The correlation between the center effect for 1983 and 1984 was 0.36, which was statistically significant at conventional levels. This suggests some intertemporal stability in center effects.

Cicciarelli (1985) assessed kidney graft survival at 80 centers that had performed at least 100 first cadaver grafts. Centers were classified into three categories based on their graft survival rates—excellent (over 55 percent), good (45–55 percent), and fair (less than 45 percent). The centers tended to remain in the same category over time, and rankings by center in second transplant survival and living-related transplants were similar to those for first cadaveric transplants. Cox analysis revealed that the center effect was more important than prior transfusion, HLA matching, and other risk factors. Excellent centers transfused more of their patients with a higher number of units than fair centers. Excellent and good centers tissue typed for DR and matched a higher percentage of their patients. Excellent centers matched HLA-A,B comparatively often. Cyclosporine therapy resulted in an increase in graft survival in excellent centers, but had a neutral effect in fair centers over other immunosuppressants. Other factors—such as race, ischemia times, cytotoxic antibody, original disease, and age of recipient—did not account for variations in outcomes among the center categories.

Benlahrache et al. (1987) analyzed data covering 1982–1986 from 71 centers. They also categorized centers as excellent, good, and fair, but they used different survival cutoff rates to subdivide the sample. They found no difference in mean graft survival by the number of first cadaver transplants of the center, but, as in previous research, the survival rates for the low-volume centers fluctuated more, as would be expected to occur by chance. A differentiating characteristic of the excellent centers was their success in using cyclosporine. The difference between the center groups began to increase in 1984, which coincided with the introduction of cyclosporine at U.S. centers. Thus, the difference in outcomes appears to be in posttransplant management of cyclosporine-treated patients.

Fair centers showed no significant improvement with cyclosporine. Graft survival rate for non-cyclosporine-treated patients did not differ significantly among the center types. There were no statistically significant differences among center types in the survival of living donor transplants whether cyclosporine was administered to the organ recipient or not. Patient demographic characteristics, including recipient age, race, sensitization, and HLA matching were very similar among the center groups. However, excellent centers transplanted proportionately fewer patients without blood transfusions prior to the transplant operation than did good or fair centers. HLA matching was more closely related to graft survival at fair than at the other types of centers.

Cost. Arguments for the consolidation and elimination of duplicated facilities have often been based on potential cost savings. In principle, three types of savings may be achieved (Sloan 1988). First, to the extent that there are economies of scale in the provision of hospital care in general or of specific types of hospital-based services in particular, forcing consolidation into larger production units will lower the cost per unit of output. Second, capacity reductions may reduce utilization. Third, by limiting the proliferation of new and sophisticated technologies, the growth in cost per day of care may be reduced. It is not necessary to conduct research to know that by severely limiting the capacity of the system to perform transplant procedures, the supply of organs would at some point no longer be the constraining factor in the number of transplants performed. The existence of scale economies, however, cannot be similarly deduced but must be assessed by empirical analysis.

Some scale economies in the provision of hospital care in general and for particular hospital services have been documented (Lipscomb et al. 1978; Friedman and Pauly 1983; Schwartz and Joskow 1980; Vitaliano 1987). However, it appears that scale economies are not an important source of hospital cost variation, and the potential savings from limiting provision of services to larger units appear to be small. Schwartz and Joskow (1980) computed the potential savings from fully complying with the standards established by the 1978 Health Planning Guidelines (U.S. DHEW 1978) for CT scanners, open-heart surgery, cardiac catheterization, therapeutic radiology, and beds. Their best estimate was that less than 2 percent of total hospital expenditures would have been eliminated if the guidelines had been followed in full for the above items.

One reason that larger units are not appreciably cheaper (even for so specialized and sophisticated a service as open-heart surgery) is that many of the services used by heart surgery patients—such as the blood bank, the laboratory, and radiology—are not specialized to such patients but are used by patients with a wide variety of diagnoses. Furthermore, investments in plant and equipment by the hospital may be minimal, especially if, for example, the hospital is already doing cardiac catheterization and has a coronary care unit. The major investment is likely to be in the acquisition of specialized personnel. An analogous argument can be made for transplant procedures.

Held et al. (1986) assessed the effects of the number of transplants on two measures of cost—Medicare reimbursement per case and charges per case. The same binary specification for volume was used as in the outcomes analysis described above. Using the reimbursement measure, there were economies of scale. Centers performing fewer than ten transplants received a per case hospital reimbursement that was from 25 to 33 percent higher on average than their counterparts with 68 or more transplants received. In contrast, there were no differences in the dependent variable by volume using the charges per case measure. Apparently Medicare disallowed a higher percentage of charges at the high-volume centers.

A study of the productivity of dialysis facilities by Held and Pauly (1983) revealed some economies of scale, which were somewhat higher than the economy

of scale estimates obtained for hospitals as a whole (compare their estimates with Vitaliano 1987, for example). The authors were cautious about this result for methodological reasons and the result should thus be appropriately viewed as tentative.

Empirical analysis of kidney transplant outcomes and charges

There is virtually no direct evidence on the influence of various provider characteristics on the outcomes and cost of transplant procedures. To isolate the effects of provider characteristics, it is necessary to take account of patient characteristics influencing patient outcomes and cost. Cost data on kidney transplant programs are unavailable; thus we will assess variations in charges. The dependent variables in our outcomes analysis are kidney graft survival, posttransplant patient survival, and the number of rejection episodes per three-month period after the transplant operation. It is too early to conduct a meaningful empirical assessment of procedures other than kidney transplants, as UNOS only began to collect the necessary data on other transplant procedures in October 1987.

Methods of procedure. *Data.* The primary database for our empirical analysis of kidney patient outcomes came from HCFA's ESRD program management and medical information system (PMMIS). We obtained from HCFA information on over 15,000 patients who received kidney transplants during calendar years 1985 and 1986 and followed these patients on a quarterly basis through 1987. Thus, the data recorded a follow-up period from 12 to 36 months. A form was completed on each patient at the time of the transplant and separate follow-up reports were completed each quarter. HCFA merged the data from the two sources and supplied us with a file that used the patient as the unit of observation. HCFA also identified the name of the facility at which the patient received the transplant and the name of the patient's surgeon. A total of 430 different surgeons were listed on patient records as having performed kidney transplants during 1985–1986 (about 18 operations per surgeon per year). We developed a measure of volume per surgeon and merged this information onto each patient's record. In addition, HCFA provided unpublished data on the number of kidney transplants performed per year by facility during 1984–1986. We merged these data and information on hospital bed size and teaching status into each patient's record. The bed size and some of the teaching status information came from American Hospital Association annual hospital surveys for 1985 and 1986. A list of flagship teaching hospitals was obtained from the American Association of Medical Colleges (AAMC) for purposes of an earlier study. The AAMC defines a flagship teaching hospital either as one owned by a medical school or as a separate nonprofit or public hospital at which the medical school department chairs and hospital chiefs of service are typically the same person. (See Sloan 1986 for comparative data on flagship versus other short-term general hospitals.)

The PMMIS data did not have information on charges. The data for our analysis of charges and length of the stay of the admission at which the kidney transplant

was performed came from the epidemiologic database (5 percent Medicare hospital sample) constructed by HCFA to monitor changes in the quality and cost of care in the Medicare population under prospective payment and peer review systems. The file made available by HCFA to Vanderbilt contained information on inpatient charges and other characteristics of the stay (such as length) as well as patient survival. Inpatient charge information was available for all of the patient's hospital admissions for up to two years following the kidney transplant procedure. The file covered slightly under 400 transplant cases for calendar years 1984 and 1985. Patients were followed through the end of 1985. Although the file contained much less clinical information than the data on transplant patients from PMMIS, some new information on patients' comorbidities and demographic characteristics was provided. Also, with only about 400 cases, our tests of statistical significance lacked the power of our outcome analysis. We merged hospital-specific information on the number of transplants performed during the year and data on hospital bed size, teaching status, and location as well as a wage index onto the Medicare file.

Specification. Hazard models were estimated using dependent variables of time to graft failure or censoring or, alternatively, time to death or censoring. In the graft failure analysis, if the patient died we considered the graft to have failed even if the death had another cause. It appears that previous studies treated such observations as "censored" because no graft failure was reported; this procedure has the potential of lumping such cases with the "successes." A third dependent variable in our analysis of outcomes was the number of rejection episodes per quarter experienced by the patient after receiving the kidney transplant. We estimated separate equations for living donor and cadaveric donor transplants, using 3,405 recipients of kidneys from living donors and 11,794 recipients of kidneys from cadaveric donors in the sample.

The charges and length-of-stay analyses had three dependent variables: first (transplant) admission charges, total inpatient charges from date of first admission until death or until 31 December 1985, and first admission length of stay. We took the natural logarithm of each dependent variable. A total of 374 kidney transplant patients were included in the charges/length-of-stay database.

Explanatory variables for the outcomes and for the charges and length-of-stay analyses are shown in Tables 1 and 2, respectively. A much more limited set of variables was available from the Medpar file. The Medpar file did not contain a variable distinguishing living from cadaveric donor transplants.

Estimation. The hazard models presented below were estimated using a specification of the hazard rate that differs from the Cox specification in two fundamental ways. First, when holding other factors constant, the probability of failure is not constant over the length of the spell—i.e., where there is time dependence, the Cox specification requires that the coefficients of the time parameters be estimated sequentially. It is therefore impossible to obtain correct standard errors for these estimates. The specification used in analysis allowed for simultaneous es-

Table 1. Explanatory Variables Included in Analysis of Kidney Transplant Outcomes

Facility	
Number of transplants performed at hospital during year:	≤ 10[a]
	11–33
	34–67
	68–99
	100–167
	≥ 168
Number of transplants performed by patient's surgeon during year:	< 6[a]
	6–10
	11–33
	34–67
	68–99
	≥ 100
Flagship teaching hospital	
Non-flagship member of Council of Teaching Hospitals (COTH)	
Other hospital[a]	
Number of hospital beds	
Patient (recipient)	
Sex: Male	
Female	
Race: Asian	
Indian	
Black	
Missing	
White[a]	
Age at time of transplant:	< 15[a]
	15–24
	25–34
	35–44
	45–54
	≥ 55
Number of transplants:	1[a]
	≥ 2
PRA at transplant:	0[a]
	1–59
	≥ 60
	Missing
Peak PRA:	0[a]
	1–59
	≥ 60
	Missing

Table continues on following page.

Table 1. Continued

HBsAg status at time of transplant:	Negative[a]	
	Positive	
	Unknown	
CMV (cytomegalovirus) status:	Antibody not present[a]	
	Antibody present	
	Missing	
Creatinine decline without dialysis at one week posttransplant:	No[a]	
	Yes	
	Missing	
Primary diagnosis leading to kidney failure:	Diabetes	
	Hypertensive nephropathy	
	Glomerulonephritis[a]	
	Cystic diseases of kidney	
	Other diseases	
Treatment		
Immunosuppression at time of transplant:	Cyclosporine	
	Imuran, cytoxan, prednisone, medrol	
	Antithymocyte globulin	
	Irradiation/solumedrol	
	Other	
	Unknown	
Blood transfusion prior to transplant:	No[a]	
	Yes	
	Missing	
Donor and donor/patient		
Number of haplo matches between donor and patient (recipient)		
Haplo dissimilar[b]		
HLA identical[b]		
Haplo identical[b]		
Identical twins[b]		
Match unknown[b]		
Time		
Time (number of months elapsed since transplant)[c]		
Time squared[c]		
Year of transplant:	1985[a]	
	1986	

a. Omitted reference group.
b. Only included in analysis of transplants from living-related donor.
c. Excluded from analysis of rejection episodes.

timation of all the parameters so that all standard errors are correctly estimated. We included both a linear and a squared term for time to allow for the possible nonmonotonicity of time dependence.

Table 2. Explanatory Variables Included in Analysis of Inpatient Charges

Facility	
Number of transplants performed at hospital during year:	< 34[a]
	34–67
	68–99
	100–167
	> 168
Hospital classification:	Flagship teaching hospital
	Nonflagship member of Council of Teaching Hospitals
	Other hospital[a]
Number of hospital beds	
Census divisions:	New England and Mid-Atlantic
	East North Central and West North Central
	South Atlantic, East South Central, and West South Central
	Mountain and Pacific[a]
Medicare Wage Index—1984	
Hospital located in Standard Metropolitan Statistical Area (SMSA):	Yes
	No
Patient (recipient)	
Sex:	Male
	Female
Race:	Black
	Other
	Missing
	White[a]
Age at time of transplant:	0–24[a]
	25–54
	≥ 55
Primary diagnosis at time of transplant:	Chronic renal failure or unspecified renal failure
	Other[a]
Secondary diagnosis at time of transplant:	Ischemic heart disease and failure
	Diabetes
	Hypertension
	Other or none[a]
Time	
Year of transplant:	1984[a]
	1985

a. Omitted reference group.

Second, in contrast to the Cox procedure, our estimation approach allowed for the possibility of unobserved differences among patients, hospitals, and/or surgeons that may affect the probability of failure. Omitting the unobserved heterogeneity component biases the estimates of the time dependence parameters as well as the coefficients of any other variables that may be correlated with time.

We assume that the heterogeneity component followed a gamma distribution. Alternatively, we could have assumed a log-normal distribution, but employing this distribution would have been much more expensive computationally.

We defined the hazard function $\lambda(x, t, v)$ as

$$\lambda(x, t, v) = \exp(x, b) \times \exp(g_1 t + g_2 t^2) \times \exp(v), \qquad (1)$$

where x is a vector of observable independent variables, b is a coefficient vector, t is time, g_1 and g_2 are the time dependence parameters, and v is the unobserved heterogeneity component. Occasionally, the variance of the distribution of v is difficult to estimate. In models based on the live donor sample, the estimation converged and estimates of the variance were obtained. However, in models using the sample of cadaveric donors, the variance could not be estimated, which in this application was not important.

To evaluate the relative risk associated with a binary characteristic, one multiplies the parameter value by the binary. The antilog of the product gives the relative risk.

We also estimated hazard models using the Cox procedure. The conclusions to be drawn about the effects of facility characteristics were the same as those presented below. Our Cox program provided a measure of goodness of fit of the estimated equations.

To analyze variations in the number of rejection episodes per quarter, we first estimated equations using probit regression with a binary variable which was set equal to one if at least one rejection episode was recorded and was set equal to zero otherwise. Second, using samples of patients with at least one rejection episode, we analyzed differences in the number of episodes per quarter using ordinary least squares (OLS).

We also used OLS for our analysis of charges and length of stay. In some variants, we included a variable for the time the patient was observed in the post-transplant phase. Inclusion of this variable had virtually no impact on the parameter estimates of the other explanatory variables.

Results. In 1986, 26 (14.4 percent) of the 181 hospitals performing kidney transplants performed 10 or fewer operations. Almost an equal number performed 100 and more operations (Figure 1). As with hospital volume, there were appreciable differences in the number of kidneys transplanted per surgeon (Figure 2). Nearly half of the 391 surgeons who performed at least one kidney transplant performed 10 or fewer such operations during the year. Eight surgeons (2 percent) performed 100 or more kidney transplants. The distribution of operations performed was bimodal, with peaks at 1–5 and 11–33. Over 90 percent of these physicians performed kidney transplants at one hospital (Table 3). Less than 1 percent performed them at three, and none performed them at more than three.

We correlated all of the explanatory variables listed in Table 1 with the number of transplants performed by hospital and by surgeon. The vast majority of simple

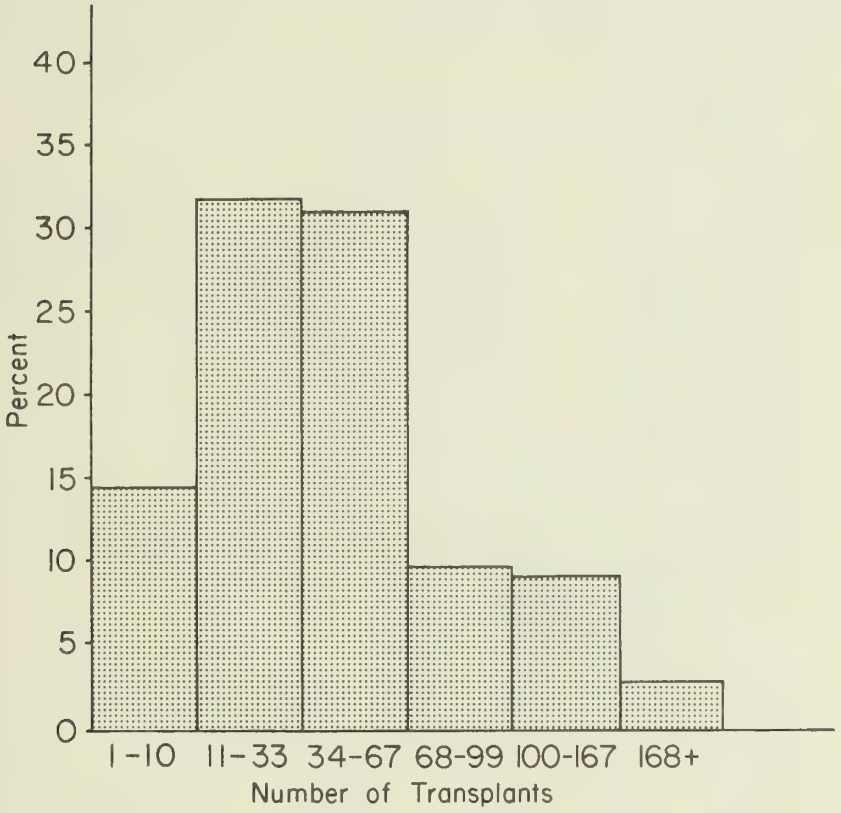

Figure 1. Number of Kidney Transplants Performed per Hospital, 1986 (Percentage Distribution)

correlations with the volume measures were less than 0.1 in absolute value. Correlations greater than this are shown in Table 4. With the large samples available for the outcomes analysis, correlations far less than 0.1 were statistically significant at the 5 percent level or better. We obtained moderately high correlations between surgeon and hospital volume (0.47 from the living donor sample and 0.39 from the cadaveric donor sample). The number of kidney transplants per hospital was higher at flagship and lower at other COTH hospitals than at other hospitals. The correlations between hospital teaching status and surgeon volume were below the critical value used for inclusion in Table 4. Most of the correlations between the volume measures and patient characteristics and treatment method were less than 0.1 in absolute value. Judging from the correlations, high-volume hospitals and high-volume surgeons were less likely to record pertinent clinical data, such as prior blood transfusions and PRA.

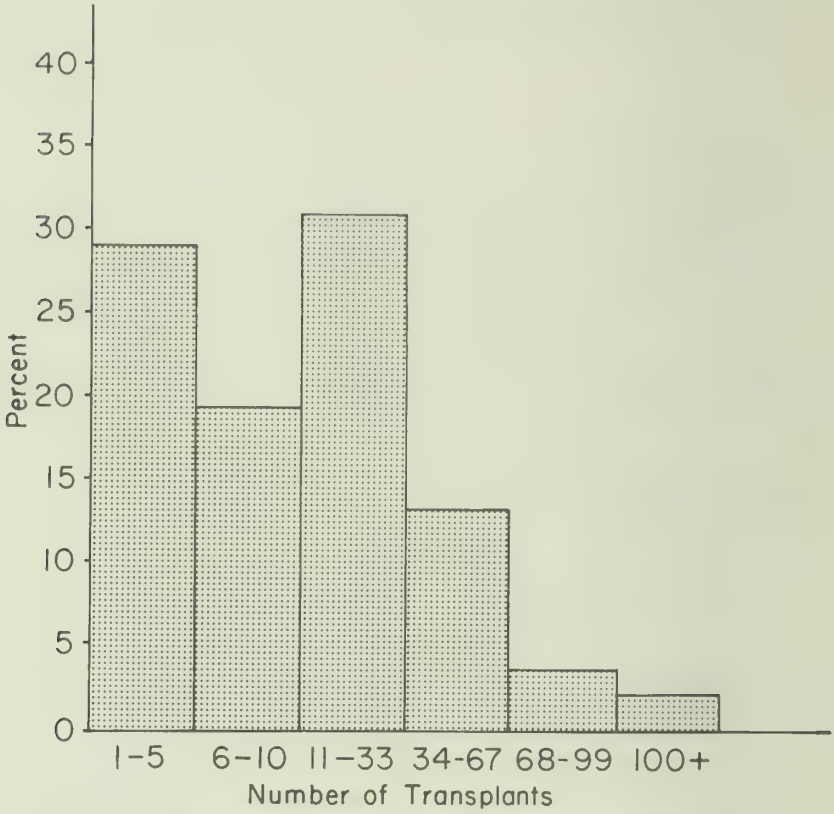

Figure 2. Number of Kidney Transplants Performed per Surgeon, 1986 (Percentage Distribution)

Table 3. Number and Percent of Surgeons Who Performed Kidney Transplant Operations in 1986, by Number of Hospitals at Which Operations were Performed

Number of Hospitals	Number of Surgeons	Percent
1	355	90.8
2	33	8.4
3	3	0.8
Total	391	100.0

Table 4. Correlations Greater than 0.1 in Absolute Value: Other Explanatory Variables with the Number of Transplants Performed per Hospital and per Surgeon

	Living Donor Sample		Cadaveric Donor Sample	
Explanatory Variable	Hospital	Surgeon	Hospital	Surgeon
Number of transplants per surgeon	0.47	1.00	0.39	1.00
Flagship teaching hospital	0.38		0.22	
Other COTH hospital	−0.27		−0.11	
PRA at time of transplant: 1–59		−0.13		−0.12
Missing	0.20	0.21	0.14	0.17
Peak PRA: 1–59		−0.15		−0.15
Missing	0.16	0.21	0.14	0.21
HBsAg status missing	0.50	0.50	0.30	0.38
CMV status: Antibody present	−0.21	−0.11	−0.11	
Missing	0.30	0.29		0.16
Creatinine decline: Yes		−0.29		
Missing	0.13	0.43		0.40
Immunosuppression:				
Imuran, cytoxan, prednisone, medrol		−0.19		−0.13
Irradiation/solumedrol	−0.26		−0.23	
Unknown		0.20		0.16
Prior blood transfusions: Yes		−0.19		−0.14
Missing		0.25		0.26
Number of haplo matches	−0.11		−0.11	0.11
HLA identical		−0.10		
Match unknown		0.40		
Year: 1986			0.10	0.11

Neither hospital nor surgeon volumes had statistically significant effects on time to graft failure or time to patient deaths when the lowest output categories were the omitted reference groups. The relative risks associated with various volume categories varied substantially (see Table 5), but the patterns of relative risk varied from equation to equation. For example, for living donor time to graft failure, the very low-volume hospitals and surgeons tended to be relatively poor performers. Volume had the opposite effect on time to death of recipients of kidneys from living donors. Any volume category can be used as the omitted reference group. We obtained a few statistically significant differences when middle-volume categories were used as the omitted reference groups.

Flagship and other COTH hospitals performed relatively well in the analysis of living donor graft and patient survival but not in the analysis of outcomes for ca-

Table 5. Estimated Effects (Relative Risk) of Volume and Hospital Characteristics on Time to Kidney Graft Failure and Time to Death

	Grafts from Living-Related Donors		Grafts from Cadavers	
	Time to Failure	Time to Death	Time to Failure	Time to Death
Annual number of transplants per hospital				
≤ 10	1.00	1.00	1.00	1.00
11–33	0.44	3.64	1.05	1.09
34–67	0.56	2.63	0.80	0.92
68–99	0.49	2.63	0.86	0.80
100–167	0.39	2.34	1.97	0.79
≥ 168	0.45	9.05	0.89	0.79
Flagship hospital	0.70	0.54	1.02	1.02
Other COTH hospital	0.65	0.59	0.83	1.01
Annual number of transplants per surgeon				
≤ 5	1.00	1.00	1.00	1.00
6–10	0.96	2.13	1.13	1.41
11–33	0.69	1.53	0.86	1.32
34–67	0.93	1.99	0.78	1.20
68–99	1.13	2.53	0.70	1.26
≥ 100	0.81	1.45	0.92	0.93

Note: None of the parameter estimates were statistically significant with the reference category hospital volume ≤ 10, nonteaching hospital, and surgeon volume ≤ 5. With the 68–99 volume group as the reference category, the difference between the 11–33 and 68–99 groups was significant at the 1% level for cadaveric patient deaths. With the 34–67 surgeon volume category as the omitted reference group, the 6–10 group was significantly higher for cadaveric graft failure and ≥ 100 surgeon volume was significantly lower for cadaveric patient death.

daveric donors. Because of the hazard model used, omitted factors should not affect the estimated effects of the included explanatory variables.

Many of the other explanatory variables were statistically significant. Judging from the pseudo-R^2s available from the estimated hazard rate functions estimated with the Cox procedure, the equations accounted for about one-sixth of the variation in the dependent variables. (These results are not presented in this article, but they are available from the authors on request.)

Judging from the signs on the estimated parameters, the very low-volume hospitals and surgeons did worse in terms of rejection episodes (Table 6). But any effect of volume was only observed for very low volume.

We found some differences in inpatient charges and length of stay according to the number of transplants performed per year at the facility. From the estimated parameters on the annual number of transplant variables, we found that hospitals with medium volumes (the 68–99 volume range) tend to have lower charges and

Table 6. Estimated Effects of Volume and Hospital Characteristics on Frequency of Kidney Graft Rejection Episodes

	Grafts from Living-Related Donors		Grafts from Cadavers	
Explanatory Variables	Probability[a]	Number[b]	Probability[a]	Number[b]
Annual number of transplants per hospital				
11–33	−0.137	0.0063	0.014	−0.044
	(0.171)	(0.053)	(0.190)	(0.030)
34–67	−0.038	0.013	−0.133	−0.064**
	(0.171)	(0.053)	(0.189)	(0.030)
68–99	−0.049	−0.025	−0.201	−0.110*
	(0.182)	(0.056)	(0.200)	(0.031)
100–167	−0.239	0.126**	−0.195	0.013
	(0.188)	(0.060)	(0.208)	(0.032)
⩾ 168	−0.107	0.212**	−0.179	−0.032
	(0.197)	(0.062)	(0.210)	(0.032)
Flagship hospital	0.255*	−0.031	0.317*	0.005
	(0.082)	(0.026)	(0.085)	(0.014)
Other COTH hospital	0.283*	−0.021	0.352*	−0.023***
	(0.088)	(0.028)	(0.089)	(0.014)

Table continues on following page.

Table 6. Continued

Annual number of transplants per surgeon				
6–10	−0.185	−0.104***	−0.067	0.031
	(0.189)	(0.057)	(0.153)	(0.023)
11–33	−0.133	−0.083	−0.099	−0.006
	(0.171)	(0.052)	(0.137)	(0.021)
34–67	−0.110	−0.075	−0.079	0.005
	(0.176)	(0.053)	(0.143)	(0.022)
68–99	−0.150	−0.098***	−0.152	0.007
	(0.186)	(0.056)	(0.158)	(0.024)
≥ 100	−0.477*	−0.092	−0.083	0.022
	(0.194)	(0.060)	(0.170)	(0.026)
Number of cases	3,405	1,207	11,794	5,141
R^2	—	0.24	—	0.14
$\bar{R}^2$	—	0.20	—	0.13

* Statistically significant at the 1% level (two-tail test).
** Statistically significant at the 5% level (two-tail test).
*** Statistically significant at the 10% level (two-tail test).

a. Our probit program could not run on the full cadaveric sample. Hence, we estimated the equation using a 25 percent sample. The number of observations shown is for the full sample. The corresponding OLS regression was run with 5,141 observations.

b. Regression is limited to cases with at least one rejection episode.

Table 7. Estimated Effects of Volume and Hospital Characteristics on Inpatient Charges and Length of Stay

Explanatory Variables	Inpatient Charges: First Admission	Inpatient Charges: All Admissions Up to Two Years	Length of Stay, First Admission
Annual number of transplants per hospital			
34–67	−0.106	0.009	−0.117
	(0.131)	(0.298)	(0.152)
68–99	−0.280**	−0.155	−0.258***
	(0.132)	(0.300)	(0.154)
100–167	−0.120	−0.177	−0.170
	(0.133)	(0.304)	(0.157)
≥168	−0.118	−0.142	−0.134
	(0.133)	(0.301)	(0.156)
Flagship hospital	0.059	0.171	0.119
	(0.081)	(0.185)	(0.096)
Other COTH hospital	−0.008	−0.022	0.097
	(0.088)	(0.201)	(0.103)
Bed size	−0.00003	−0.0000	0.0000
	(0.00009)	(0.0002)	(0.0001)
Medicare wage index	0.972*	1.61*	—
	(0.214)	(0.48)	—
Number of cases	374	374	374
R^2	0.20	0.10	0.12
$\bar{R}^2$	0.15	0.04	0.07

* Statistically significant at the 1% level (two-tail test).
** Statistically significant at the 5% level (two-tail test).
*** Statistically significant at the 10% level (two-tail test).

stays than hospitals with fewer or more transplants (Table 7). More specifically, inpatient charges for the admission at which the transplant was performed were 28 percent lower on average than for the omitted reference volume category (less than 34 transplants per year). We did not have a sufficient number of observations to distinguish among institutions in the 1–10 from the 11–33 volume groups as in the outcomes analysis. First admission charges in the 34–67, 100–167, and 168-plus volume categories were 10 to 12 percent lower on average than those for the hospitals in the 1–33 volume group. There were no differences in charges according to hospital teaching status and bed size, holding other factors constant. As expected, charges tended to be higher in areas with high wage rates. Not surprisingly, the parameter estimates were less precisely estimated in the regression that included inpatient charges for all admissions up to two years post-transplant. One reason is that a patient could be admitted to another hospital and/or for a reason other than for his kidney disease.

Lengths of stay were 26 percent lower on average in hospitals with volumes of 68–99 than in those with fewer than 34 transplants. Stays were also lower in hospitals with volumes of 100 or more, but the parameter estimates were smaller than those for the 68–99 volume group and were not statistically significant at conventional levels.

Discussion

It is often said that it is more feasible to manage the delivery of new technologies than the delivery of established technologies since there are fewer entrenched parties to resist constructive change. On the other hand, there is less direct empirical evidence on which to base such change in the case of new technologies. It is usually necessary to base policy on practical experience with the new technology and on inferences from empirical findings from research on existing technologies. With the notable exception of kidney transplantation, this is true of transplantation policy as well.

While kidney transplantation shares some features with transplantation of other organs, such as the management of immunosuppression, there are also differences that are pertinent to the design of a regionalization policy for delivery of care. In the case of kidneys, one payer—Medicare—covers virtually everyone. Thus, Medicare's payment criteria must be determinative. Although in practice, Medicare may take a leadership role in establishing payment criteria, Medicare will at most pay for a minor portion of the expenditure for the other types of transplants.

Medicare has a statutory obligation to cover the care of ESRD patients. Transplantation is often a less costly alternative than dialysis (Eggers 1988). Patients with other failing organs are not universally covered, and the alternative to transplantation for the patient is death. From strictly a payment perspective, death is the less costly alternative. Creating contrived scarcities of resources for treatment is a socially and politically acceptable form of rationing. Thus, although the supply of organs is now the binding constraint, there is pressure from some quarters (most directly from third-party payers) to limit the number of organ transplantation sites. Governments at various levels are likely to feel such pressures, as Congress did in 1984 from the commercials and the Blues, since private parties cannot effectively bar entry of new facilities. Such pressures are likely to build. As of December 1986, hearts were being transplanted at 94 hospitals, heart/lungs at 14, livers at 41, and pancreata at 27. The mean numbers of transplants per facility were far lower than for kidneys in 1986: 14.6 for hearts, 3.2 for heart/lungs, 22.5 for livers, and 5.1 for pancreata (unpublished data from the U.S. Department of Health and Human Services, Office of Health Technology Assessment). This is in contrast to the 39.8 kidney transplants performed per center in 1986 (as derived from PMMIS). Of course, the mean values obscure the fact that for at least some procedures, there are a handful of very high-volume centers. Unfortunately, except for kidneys, data on the number of transplants performed by facility are not publicly available. Over three times as many kidneys were transplanted as other organs combined.

Once they are excised from the human body, organs are viable for relatively short periods of time. The kidney, however, is viable for the longest time, up to 72 hours. For hearts, the time is considerably shorter, between three and four hours (Evans 1983: 65). Even with private jet transportation, this consideration may limit transplant centers to certain geographic locations.

In spite of these differences, some generalizations about the newer extrarenal transplant technologies which are useful to policymakers, payers, and others who are interested in the transplant delivery system can be made from the experience with kidney transplantation. The literature on outcomes and cost from nontransplant technologies of the type reviewed above is of some, albeit more limited, use.

Experience with regionalized networks of any type of health service has been extremely limited in the United States. The only networking in the transplantation field currently is between the regionalized organ procurement agencies and hospitals delivering transplants; and, as noted above, hospitals have been able to deal with procurement agencies outside of their regions. ESRD implemented network catchment areas, but these networks faced the practical problems reported above. The case for regionalizing kidney transplants was not well documented, but was based on the same foundation as other government-mandated coordination efforts, namely the idea that planning and cooperation were good things to do.

Important problems such as those addressed by proponents of regionalized networks clearly exist. In particular, the absence of capacity to treat transplant patients (both while patients are waiting for an organ and after the operation) is a policy issue that appears to be getting surprisingly little attention at present. Perhaps because of the low number of transplants performed per year it is not difficult to manage patients postoperatively, even at long distances. However, if the number of transplants performed annually were to grow substantially, there is reason for concern about the resources available to transplant patients who live in small and medium-sized communities, especially remote ones. To date, regionalization models that have been proposed for transplantation have not encompassed community-based posttransplant care.

A regionalized network is only one of several approaches that might be considered for the nonsurgical care of transplant patients. The main risk of formal networks stems from the possible monopolization of care. If a patient in a given locality is locked into one provider that directs care from a distant transplant center, higher prices, lower output, and even higher-quality adjusted prices are a likely consequence.

Alternatively, care might be delivered by the nonsurgical specialists who serve as agents (brokers) for the patient located more closely to the transplant patient's home. This type of specialist would be expert in immunosuppression and its complications and need not specialize in an organ system. This specialist would be the principal point of contact with the patient's usual physician. Over time, by observing outcomes and patient satisfaction from a large number of transplants performed at a variety of hospitals, the specialist would be well positioned to advise the patient and/or payer about the site of care. In some cases, the payer might contract with a specialist for advice. A company might develop a chain of trans-

plant management clinics of the type developed for the treatment of alcoholism, diabetes, back pain, and arthritis. At least given present knowledge, the case for formal vertical integration between the hospital providing the transplant and the community-based provider is not strong.

Designating centers that are allowed to perform transplant operations is a more realistic possibility at the present time. There is a substantial difference between designation by a single organization and designation by a number of parties. The Task Force on Organ Transplantation (1986) recommended the former approach. In particular, it proposed that DHHS undertake a process of center designation (ibid.: 114), but the language of the recommendation implied that the federal role in center designation, except for kidney transplantation, might only be advisory. Thus, in principle, there would still be room for pluralistic designation of centers. In practice, everyone might well follow the federal lead.

The task force gave several justifications for center designation, stating that the designation of centers would potentially:

- Facilitate the development of equitable reimbursement policies.
- Assure quality patient care and cost-effective organ transplantation by concentrating transplants in those institutions most qualified to perform these procedures as demonstrated by the results of their program's outcomes.
- Minimize the unnecessary duplication of transplant facilities.
- Assure the optimal distribution and use of donor organs and minimize wastage.
- Minimize inappropriate competition for donor organs and transplant recipients among transplant centers, especially among extrarenal transplants.
- Assure that extrarenal organ transplantation occurs in conjunction with solid clinical research (ibid.: 114).

It is not clear how in practice center designation would result in "equitable reimbursement policies." While there is some link in that payment may be inequitable if certain needy patients are denied geographic access to a transplant, financing policies are conceptually distinct from center designation. In fact, simply designating centers without providing funding for placing facilities in "underserved" areas may actually result in less equitable reimbursement. Possibly one would expect a designated center to use its monopoly profit to cross-subsidize the care of transplant patients without insurance coverage. But there is no guarantee that monopolies would allocate their profits to this purpose.

A second set of justifications for center designation appears to be based on a "destructive competition" argument. If centers were to compete for patients, they may do so by using inappropriate methods. Possibly the winners will not be the best. Since there is no empirical evidence either way, this argument cannot be dismissed entirely. Yet there are risks to franchising and horizontal agreements (consortia) among centers as well—namely, the effects of monopolization—and, given scarce organs, there must necessarily be a rationing process. One cannot be sure that rationing by a monopolist is necessarily better than rationing under

conditions of competition. Can we really be sure that only the most needy will receive transplants under a monopolistic scheme? Consortia may protect "weak sister" members whom the market would otherwise eliminate.

A related argument deals with unnecessary duplication. This argument has merit in the presence of documented economies of scale in the provision of transplant services. We did find that charges were lowest in facilities with medium-level volumes, and they tended to be lower in the large- than in the small-volume facilities. This finding suggests that in a competitive environment, the very low volume facilities may have to expand their output or leave the field. The comparative efficiency of medium-volume centers does not provide a rationale for forced horizontal integration. In fact, on a charge or cost basis, consortium members may do worse.

The rationale for designating to assure receipt of high quality and efficiently provided services is legitimate. The main question is how best to distinguish such facilities from the others. There are three non–mutually exclusive approaches. One may base choice of site on characteristics of the site, such as volume of care provided, affiliations (such as with a medical school), and qualifications of physicians and other staff. One may judge centers by their results, such as patient outcomes and charges. Finally, one may rely on in-depth reviews of center performance.

As seen above, empirical research has not isolated provider characteristics that are systematically associated with good outcomes in the field of kidney transplantation. Certainly, judging from our research and that of others, there is no basis for an assertion that the high-volume hospitals and surgeons performing transplants achieve better results. The general literature suggests a hospital volume effect more strongly than a surgeon volume effect on patient outcomes, but the underlying mechanism through which higher facility volume works has not yet been identified. In sum, such characteristics are crude indicators at best.

Some payers, lacking more direct information, might want to designate sites on volume anyway. If one had to choose between an empty Chinese restaurant and a full one, most of us would probably select the latter, especially if there were a lot of Chinese in the restaurant. Similarly, if a number of physicians (who are presumably better informed about the choices than are many individual private payers) routinely refer more of their patients to one center than to others, perhaps this is information worth considering. However, it is different when a public agency limits entry based on such indirect evidence of quality of care.

The notion of monitoring patient outcomes directly is appealing, and large differences in graft and patient survival by center have been observed. Why use proxies when it is possible to observe the real thing? Monitoring outcomes has two problems. The first is isolating the "bad apples" when both the number of cases performed by the center and the probability of an adverse outcome are low. Luft and Hunt (1986) calculated the number of deaths consistent with a statistically significant poor outcome (that is, the facility can correctly be identified as a "bad apple" based on its own results). If the expected death rate is 0.20 as determined

by a national study of deaths at discharge, for example, and the facility performs five cases per time period (say, a year), it will be necessary to observe a 60 percent death rate to conclude that the hospital performed below the national average. With 100 cases, 26 deaths would be sufficient. At current volume levels of all but renal transplants, it will not be possible to segregate the "bad apples" on the basis of poor outcomes alone.

A second problem is patient selection. If good outcomes are the criterion for designation—or, for that matter, for favorable publicity—one may expect hospitals and surgeons to reject the higher-risk transplant patients. Good outcomes may reflect high quality, but they may also reflect favorable selection. It is appropriate for providers to be choosy, but perhaps not too choosy. Also, selection may systematically work to the advantage of certain groups. For example, our statistical analysis revealed that the graft failure rate is higher for black diabetics than for white nondiabetics. Exclusive reliance on outcome data for center designation might well lead to discrimination, which is socially undesirable.

Patient outcome data should be used as a screening device to determine which centers' performance should receive detailed scrutiny, including detailed examination of clinical records. Although in-depth scrutiny is expensive, so is the cost per transplant procedure. But the notion of such detailed review raises important questions in its own right. First, who should perform the reviews? Decertification of a center based on a review by a center's competitors could, depending on the circumstances, make the reviewers and perhaps the payer liable under antitrust laws. The geographic market for transplant procedures is likely to be large, so many potential experts are likely to be competitors. Fear of litigation may make the reviewers and payers reluctant to recommend decertification. Even without the threat of litigation, decertifying a colleague's facility is likely to violate professional norms. Second, who should sponsor the reviews? Reviews by a single public agency would tend to establish a single uniform approach in an area in which diversity and innovation are highly desirable. On the other hand, it may be difficult and inefficient for small payers to undertake reviews or sponsor reviews on their own. Yet one may envision the emergence of a new industry composed of firms specializing in making quality-of-care assessments. Small payers would contract with such firms for this purpose. Opinions about quality, as well as the relative weights given quality versus other objectives, may be expected to differ among payers and the payers' customers, such as employee groups. Thus, it is likely (and desirable) that assessments will differ. Pluralistic designation is to be preferred by far to no center designation at all.

As indicated earlier, UNOS has a policy of reviewing the quality of care of all facilities with survival rates in the lowest 5 percent of all centers performing transplants. This percentile cutoff seems low to us. We speculate that the various parties in a pluralistic designation system could use a higher percentile cutoff. It is difficult for one organization with the power of saying yes or no to all facilities to use this power very often.

Is there a rationale for regionalization? Yes. Patients, policymakers, and payers are now appropriately more conscious of cost and quality differences among providers than previously. The data for cost and quality monitoring are better than ever. However, better data are allowing researchers to verify much of the conventional wisdom. Many of the old proxies for quality and cost do not appear to be valid. So while consumers of care should be choosy, choices made on the basis of proxies may turn out to be poor ones. And the risks inherent in granting monopolies to particular centers and/or groups of centers are substantial. Concerns about such things as the need for adequate care for patients with transplanted organs provided in proximity to where such patients live as well as the need to provide adequate access to transplants of persons who live in areas geographically remote from transplant centers have merit as bases for the notion of regionalized networks for the delivery of transplant services. But it is not clear that it is necessary to have formally vertically integrated structures in order to address such concerns.

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Government Funding for Organ Transplants

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Abstract. This paper examines the role of the federal and state governments in paying for organ transplants. The first section, descriptive in nature, presents data on the past, current, and projected payment patterns for different kinds of organ transplants under various federal and state programs. The second section, which is normative, considers the three principal arguments for and against government payment for organ transplants. These arguments revolve around efficiency, equity, and communitarian claims, and none of them is wholly satisfactory. The final section, which is policy-oriented, assumes that government financing of organ transplants will continue but will be fiscally constrained, and goes on to analyze a number of important payment policy issues in the light of broader principles. These issues relate to eligibility, comprehensiveness of benefits, reimbursement formulas, entitlement, and level of government. The paper concludes by predicting that as transplant procedures become less constrained by organ supply and more routinely performed, they will lose the privileged political position that they now enjoy and will instead be obliged to compete for scarce governmental resources with other social goods on more equal terms. Government policy should be designed to encourage this competition.

The federal government and many state governments are now fiscally committed to paying for organ transplants. Because those fiscal commitments generally take the form of entitlement programs for broadly defined, categorically eligible groups (the elderly, certain disabled persons, and the poor), they entail a large, potentially open-ended claim on public resources. As technological change continues to advance the frontiers of organ transplantation practice, that claim steadily increases. Especially during a period of severe budgetary constraint, the nature and extent of that claim are bound to become divisive political issues.

This paper re-examines the role the public has, through the federal and state governments, in paying for organ transplants. The paper summarizes the available data concerning the past, current, and projected payment patterns for organ transplants, considers the principal arguments for and against government payment for organ transplants, and analyzes a number of important payment policy issues in the light of broader principles that might be invoked to resolve them. The paper concludes by suggesting that as the existing constraints on the supply of trans-

plantable organs relax and as transplant procedures become more and more routinized, such procedures will lose their privileged political position and will be obliged to compete for scare governmental resources with other social goods. When that occurs, the moral and policy dilemmas surrounding payment policy for transplants will seem less unique, if perhaps no less difficult, than they do today.

Patterns of payment for organ transplants

The federal government began paying for organ transplants only fifteen years ago, but there has been substantial programmatic growth since then. This growth can be measured in terms of public expenditures on organ transplants[1] and the number and types of organs involved.[2]

Federal programs. The three federal payers for transplants are Medicare, the Veterans Administration (VA), and the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS).[3] Medicare pays for kidney and heart[4] transplants; with one insignificant exception,[5] it does not cover liver transplants, which it still considers experimental.[6] The VA and CHAMPUS have greater leeway in payment authority, and may pay for liver as well as kidney and heart transplants.

Medicare: Kidney transplants. The largest of these three programs is Medicare's coverage of kidney transplants, which applies to all individuals covered

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1. Although no data are available concerning the number of organ transplants that are paid for privately, the vast majority of organ transplants are governmentally funded, especially with regard to kidneys for which the end-stage renal disease (ESRD) program provides coverage without regard to age or income. Some "private pay" transplants are received by individuals not covered by the Social Security system, but the number must be fairly small and these are presumably covered, at least in part, by private insurance. According to a 1985 survey that the Health Insurance Association of America conducted of its members concerning their coverage of organ transplants under group comprehensive and major medical policies, 63 of 65 companies cover kidney transplants, 57 as a "standard practice." The comparable numbers of companies for hearts were 55 (covered) and 37 (as standard practice); for heart/lungs 45 and 26; for livers 52 and 33; for pancreata 37 and 21. Most companies indicated that they did not impose limitations based on patient selection criteria or provider (HIAA 1988).

2. The number of institutions performing transplants has also grown. See text at footnote 18.

3. CHAMPUS is an entitlement program covering dependents of active-duty military personnel, military retirees and their dependents, and survivors of people killed on active duty. The program is designed to supplement the military medical treatment system.

4. Medicare pays for heart transplants for those who rest their Medicare eligibility upon "disability" status as defined by Title II of the Social Security Act, which requires a two-year period of inability to engage in gainful employment. See text at footnote 19.

5. Medicare covers liver transplants for children under the age of seven who suffer from biliary atresia, a rare liver disease, and who meet the statutory definition of eligibility under Section 226(b)(2)(A)(ii) of the Social Security Act, which requires, among other things, that the child have been unable to engage in gainful employment for two years (U.S. DHHS 1986). Of course, very few children qualify. The two-year waiting period under Medicare runs from the date that disability benefits commence, which itself occurs five months after the date of onset. Thus the total minimum waiting period is 29 months.

6. The possibility of Medicare coverage of liver transplants is currently being assessed by the Office of Health Technology Assessment in the National Center for Health Services Research.

Table 1. Kidney Transplants Financed by Medicare

Year	Expenditures	Number of Transplants
1974	$ 31,200,000	N/A
1975	49,400,000	N/A
1976	70,200,000	N/A
1977	87,100,000	N/A
1978	109,200,000	N/A
1979	137,800,000	N/A
1980	170,300,000	N/A
1981	200,200,000	4,421
1982	226,200,000	4,917
1983	258,700,000	5,616
1984	270,400,000	6,029
1985	284,700,000	7,073
1986	N/A	8,258
1987	N/A	≈ 8,258

Source: Personal communications with Paul Eggers, Office of Research, HCFA, and with Kathy Sagel, ESRD Data Branch, HCFA.

by Social Security who suffer from end-stage renal disease (ESRD). The Medicare ESRD program is the only program for which yearly figures are available to show the evolution of governmental payment for transplants. This evolution is displayed in Table 1.

The data in Table 1 indicate a steady growth in both the number of and public expenditures for kidney transplants under Medicare through 1986. The most dramatic growth rates occurred between 1982 and 1983, when the number of transplants increased by more than 14 percent, and between 1985 and 1986, when they increased by almost 17 percent. Perhaps the most striking fact is that according to unpublished data, the number of kidney transplants remained essentially unchanged in 1987. The significance of this apparent leveling off in the pattern of growth has not yet been determined.[7] (It is worthy of note that the number of new

7. Telephone conversation with Paul Eggers, Office of Research, HCFA, 1 June 1988. Several theories have been advanced to account for the 1987 figure. One is that during 1987 the organ procurement agencies whose acquisition activities are paid for by Medicare were being consolidated and reorganized to comply with new federal requirements and thus were in a state of flux that may have impaired their operating efficiency. A more troubling theory is that some states that adopted required request laws may have been implementing them in ways that created a backlash among potential organ donors. It is also possible that these data simply reflect the exhaustion of voluntary donor activity prior to the full implementation of those laws and prior to recent improvements in handling multiple-organ situations. Another possibility is that the earlier growth reflected a one-time effect of technological improvements, such as in tissue typing, on a backlog of potential transplant recipients who could benefit from it. Yet another explanation focuses on the significant fact that two-thirds of the growth in kidney transplants since 1984 has occurred in newly established transplant centers. This explanation emphasizes that existing transplant centers may be operating at near capacity and that few new centers were

patients receiving kidney dialysis, as distinguished from transplants, has grown rapidly throughout this period. The new patient population rose from 19,300 in 1981 to 26,400 in 1984, 29,100 in 1985, and 30,700 in 1986, with the 1987 figure expected to show continued growth in line with this historical pattern.[8]) Total Medicare expenditures on kidney transplants also showed continued growth, although the rate of growth slowed somewhat between 1983 and 1985.[9] Neither expenditure figures for 1986 and 1987 nor projections of future expenditures are yet available.

The Health Care Financing Administration (HCFA) has been developing a model to project the future growth of the ESRD program, which includes very crude estimates of the number of kidney transplants as well as of patients on kidney dialysis. Continued growth is anticipated.[10]

Medicare: Heart transplants. Payment figures are not available for Medicare-financed heart transplants, but the number of such transplants has steadily increased, especially since HCFA's regulatory decision in April 1987 to cover heart transplants in approved medical centers.[11] Twenty-three transplants were performed from 1973 to 1979, while fifteen were performed from 1981 to 1983. In 1987 and 1988, Medicare has paid for about 30–50 heart transplants. Since the estimated average cost of a heart transplant is $100,000–$110,000, Medicare is now spending in the range of $2–$3 million per year for that purpose.[12] This figure

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established during 1987. (Telephone conversations with Paul Eggers, 1 June 1988; with Myron Genel, associate dean for governmental and community affairs, Yale Medical School, 10 June 1988; and with Gary Friedlaender, chairman of the Department of Orthopedics and Rehabilitation, Yale Medical School, 13 June 1988.)

8. The most striking component of this growth in dialysis has been for recipients aged 75 years and older. From 1981 to 1986, the number of those individuals on dialysis was increased annually by 23 percent, even though their survival rate declined. The total number of patients on dialysis in 1986 was 93,500. (Telephone conversations with Paul Eggers, 1 June 1988 and 1 August 1988.)

9. This may have reflected a declining average cost per transplant, but the expenditure data in Table 1 are so aggregated that it is difficult to tell. Those data refer to the Medicare expenditures for patients who have received kidney transplants during that year. They include the costs of organ acquisition, transplant-related hospital stays, physician and related fees, aftercare paid for by Medicare, dialysis for those transplant recipients who must return to it, and all other hospital stays for which Medicare pays, whether kidney-related or not. (In fact, the vast majority of this last category of expenditures is believed to be kidney-related). They do not include the cost of immunosuppressive drugs, which Medicare began paying for in 1986. (Telephone conversation with Paul Eggers, 1 June 1988.) Because the cost of maintaining patients with successful kidney transplants is one-third that of maintaining patients on dialysis, the increased expenditures for transplants will be offset somewhat by the amounts saved by not having those patients on dialysis. In addition, the quality of life is thought to be better for transplant recipients than for dialysis recipients (Eggers 1988).

10. Paul Eggers, who is building the model, projects low, middle, and high estimates for the year 2000 of (respectively) 12,000, 15,000,and 21,000 kidney transplants, and 44,000, 51,000, and 72,000 dialysis patients. The transplant projections assume no change in organ supply or in survival rates. Eggers emphasizes the arbitrary nature of these projections. (Telephone conversation, 1 June 1988.)

11. 52 Fed. Reg. 10,935 (1987). That decision was retroactive to October 1986.

12. Telephone conversation with Joel Broida, Office of Research and Demonstration, HCFA. See also Battelle (1984).

does not include the cost of immunosuppressive drugs, which Medicare has covered since 1986 for one year following the transplant.[13]

There is some inconsistency between different projections of future HCFA expenditures for heart transplants. In April 1987, HCFA projected increases in annual expenditures for heart transplants of up to $20 million under Medicare and another $5 million for the federal share of Medicaid expenditures for the next few years.[14] In 1984, however, a federally funded study published much higher estimates of over $47 million for 1989, assuming no significant increase in organ supply (Battelle 1984).

Veterans Administration: Kidney, heart, and liver transplants.[15] The VA has not prepared either transplant expenditure data or a complete time series on the number of transplants each year. It paid for 4,189 kidney transplants between 1971 and 1987, mostly in its own facilities. The number of transplants financed by the VA in 1987 was approximately 300, which is roughly the same as the number in previous years. Current VA costs for kidney transplants average approximately $30,000–$35,000 per transplant, with an annual expenditure total of approximately $10 million.

The VA paid for 256 heart transplants between 1981 and 1987. During 1988, however, its annual rate of transplants has increased over that of previous years. Current VA costs for heart transplants average approximately $62,500, which implies a 1987 expenditure total of roughly $5.5 million. The VA also pays for liver transplants; between 1984 and 1987, the VA paid for 38 of these, spending approximately $5.5 million during that period. Like Medicare and CHAMPUS, the VA also pays for immunosuppressive drugs.

CHAMPUS: Kidney, heart, and liver transplants.[16] Like the VA, the CHAMPUS program does not prepare annual number and expenditure figures for the transplants it finances. Between 1976 and 1988, CHAMPUS paid for 24 kidney transplants, spending approximately $960,000. Between 1986 and 1988, it paid for 6 heart transplants, spending approximately $390,000. And between 1983 and 1988, it paid for 30 liver transplants, spending approximately $7.2 million.

State programs. Most state governments pay for some of the costs associated with organ transplants for low-income individuals under their Medicaid programs, and the federal government pays the balance for these transplants. There is much variation in coverage and payment policies among the states,[17] but the major ex-

13. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9335.

14. 52 Fed. Reg. 10,951 (1987).

15. Information on the VA was obtained from telephone conversations with Gerald McDonald, acting director of surgical services, VA, and Pat Waldemaier, program assistant of surgical services, VA, on 5 and 21 April 1988, and with Paul Eggers on 1 June 1988.

16. Information on CHAMPUS was obtained from a telephone conversation with Dane Wert, special assistant to the director, CHAMPUS, on 21 April 1988.

17. Most jurisdictions pay the coinsurance and deductible portions of Medicare-covered kidney

ceptions are New Jersey and California, which do not cover heart/lung transplants. The total number of organ transplants financed by state Medicaid programs during 1985–1986 was 72 hearts, 94 livers, 85 kidneys, 12 pancreata, and 3 heart/lungs.

Projections. In order to design a coherent policy on payment for organ transplants, one must be able to estimate future costs. Unfortunately, with the exception of the very crude estimates concerning future Medicare costs for kidney and heart transplants noted earlier, such projections do not now exist. Useful estimates would depend critically on assumptions concerning variables such as organ transplant success rates, changes in the transplant DRGs and other reimbursement methods, supply (which in turn depends on a variety of factors, including speed and helmet laws, public awareness of organ donation, etc.), and the number of medical centers performing transplants.[18]

In the case of heart transplants, the crucial question concerning future growth is why the number of such transplants now being performed on Medicare-eligible patients remains so low (although it is rising at a rapid rate). One answer may be that few candidates for heart transplants can satisfy the stringent definition of "disability" which is necessary to trigger Medicare eligibility for this benefit.[19] Other possible answers may relate to the slow pace of the U.S. Department of Health and Human Services (DHHS) in authorizing new centers for reimbursement and the limited supply of transplantable organs. To the extent that DHHS authorizes centers at a faster rate, the number could increase even without changes in law, technology, or supply.

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transplants (48 states and the District of Columbia) and for the costs associated with liver (40 states and D.C.) and heart (32 states and D.C.) transplants. A minority cover heart/lung (15 states) and pancreas (8 states) transplants. Almost all (47 states) cover outpatient immunosuppressive drugs. Thirty-five states pay for services associated with organ procurement. The most populous states tend to cover most types of transplanted organs as well as outpatient immunosuppressive drugs. Other payment policies also differ among state Medicaid programs. Fourteen states direct patients to specific organ transplant facilities; nine encourage patients to use in-state centers by providing guidance through evaluation teams; and four will not pay for procedures performed out-of-state. Methods of reimbursement also vary considerably. These methods include DRGs (five states); per diem (four states); percentage-of-charge (four states); payment limits (three states); for out-of-state procedures, payment based on the Medicaid rate of the state in which the transplant was performed (five states); "reasonable cost" (one state); and others (Zachary 1986).

18. As of early June 1988, there were 116 medical centers performing heart transplants, of which 18 were Medicare-approved, and 173 centers performing kidney transplants, all of which were Medicare-approved. The VA has three transplant programs. It is striking that most of the growth in the number of kidney transplants since 1984 was due to an increase in the number of new transplant centers rather than to a larger number of transplants per center. This suggests that diffusion of the technology may be critical to the future growth in transplant activity. See text at footnote 7.

19. Since few, if any, heart transplants are being performed on patients who are over 65, those who do receive them must rest their Medicare eligibility on their "disability" status. (See text at footnote 4.) Needless to say, few of the patients who most need heart transplants are able to survive for the requisite two-year period without them.

Arguments for and against government payment for transplants

Although the federal and state governments are deeply involved in paying for organ transplants, it is important to consider whether and to what extent this involvement is justified. The answer is not altogether obvious.

The federal government did not directly undertake a commitment to pay for organ transplants, at least as far as kidneys are concerned: its initial commitment was to pay for ESRD treatments. Payment for organ transplants only became federal policy when kidney transplantation came to be seen as a way to provide effective care for ESRD patients at a lower cost. This is turn led to the recruitment of organ donors, which has now been extended to other organs.[20]

Beyond this historical circumstance, there are at least four related reasons why government has accepted the responsibility to pay for most organ transplants. From the analytical point of view, some of these reasons are more convincing than others. First, the need for an organ transplant is a catastrophic, life-threatening condition. At current cost levels, few individuals could afford to purchase a remedy in the market.[21] As a society, we like to believe that we do not distribute the chance to live according to ability to pay, a principle exemplified by the plethora of government health programs.

In fact, of course, we do allow people to use their wealth to purchase access to many goods—elite private schools, cosmetic surgery, experimental therapies, residential choices, the best health care—that may enhance the quality (and perhaps even the duration) of life. We tolerate market allocation of these goods for a variety of reasons, beginning with the strong presumption in a liberal society in favor of private consumption choices. That presumption is sometimes fortified by the public's belief that it is already providing at least minimal levels of the good (e.g., education and medical care), that the choice is in a fundamental sense personal and private (e.g., residential location), or that public provision would generate too much demand (e.g., cosmetic surgery).

But organ transplants differ from these situations in another, politically salient respect, and this constitutes the second reason why government has decided to pay. In contrast to "statistical" low-visibility victims, such as the thousands of low-birth-weight babies who one can readily predict will suffer retardation from the lack of prenatal care, organ transplants benefit identifiable victims whose plights are vivid, palpable, and can be dramatically represented in the media. These individuals often elicit an outpouring of sympathy that statistical victims, who remain nameless and faceless, do not.[22] In the language of public choice the-

20. Telephone conversation with Myron Genel, 10 June 1988.

21. This argument, however, is substantially undercut by the broad coverage of transplants under private group and major medical insurance policies. (See text at footnote 1.)

22. See, e.g., Havighurst and King (1986) and sources cited at footnote 2; see also New York Times (1987).

ory (Buchanan and Tullock 1962; Olson 1971), organ transplants present an interesting instance of a familiar phenomenon: they confer benefits (on recipients and their families and friends) that would seem to be highly concentrated, while imposing costs that can readily be diffused among taxpayers and large insurance pools.

In this regard, what is interesting about the organ transplant case when compared, say, with the case of a subsidy to a favored industry is how the private benefits are often magnified and widely distributed by mass media coverage that triggers popular support for and psychological identification with the recipient. This (literally) mediated interaction between private tragedy and public rescue is not objectionable in itself; social benefits, after all, are social benefits even if they are generated by a process that favors the more aggressive and histrionic over the meek and modulated. For present purposes, however, the key point is that the combination of concentrated but expandable benefits and diffuse costs is one that politicians find especially difficult to resist.

A third reason why the federal government pays for organ transplants is more systemic. Once the government begins to support a technology, it finds it difficult to stop. Having spent a great deal of money on basic research and development on organ transplant science and technique, politicians do not wish to be accused of allowing the technology to die on the vine. They are less impressed with the economic notion of sunk costs than with the political consequences of waste and error. Assuring broad access to organ transplantation, then, becomes the clinical correlate and (in the political sense) the logical sequel to the government's earlier basic science commitment. Politicians will also point out that this investment, like the space program, has yielded some important spinoffs: a better understanding of organ physiology and disease processes, new immunosuppressive drugs, advanced monitoring techniques, and greater public confidence in science's ability to improve the conditions of life. The prospect of even greater social returns on the public's investment naturally attracts even more resources.

These reasons would not be as compelling if organ transplants were so costly that governmental budgets were severely strained by funding them. However, a fourth reason for government payment is that the cost to the federal government at current levels of transplantation activity is fiscally sustainable, hardly noticeable in HCFA's $100 billion annual budget. The effect on state Medicaid budgets is more substantial, as Oregon's earlier decision to terminate Medicaid funding for most transplants suggests.[23]

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23. Oregon agreed to continue paying for cornea and kidney transplants, although Medicare already pays for virtually all of the latter. The state, which spent $1.2 million on 19 transplants between 1985 and 1987, has now amended its decision to the extent that it will resume paying for transplants out of private donations once $100,000 is raised. Two lawsuits have also been filed (Welch and Larson 1988). Because Oregon still refuses to pay for transplants under Medicaid, efforts were made to place an initiative on the November 1988 ballot to require the state to do so (Lund 1988).

Even at the federal level, however, the government's ability to absorb the cost of organ transplants with only limited fiscal exposure may not continue much longer. A number of developments could quickly increase program expenditures to levels that would no longer be a matter of indifference to interest groups seeking alternative uses for scarce budgetary resources,[24] thus requiring some response from politicians. In particular, three expenditure-increasing developments seem not only possible but inevitable and perhaps imminent: a growth in the supply of organs, a growth in the demand for organs, and technological innovations affecting both supply and demand.

The excess demand for organs is already very large.[25] Several different mechanisms designed to increase organ supply to satisfy this demand are now in place or could soon be established. Hospitals are increasingly instituting routine inquiry and required request policies.[26] Education of the public and of medical professionals concerning organ donation has been undertaken. States are adopting legislation, such as the Uniform Determination of Death Act,[27] to facilitate organ retrieval, preservation, and donation. The Organ Procurement and Transplantation Network (OPTN) mandated by Congress[28] should increase organ supply by improving the efficiency of procurement and distribution activities.[29] Organ procurement agencies are advertising more vigorously and using state driver licensing systems and other such opportunities to reach potential organ donors.[30]

But the demand for organs is not waiting for the supply to catch up; it is also increasing steadily and will almost certainly continue to do so. Longer life spans mean a greater need for healthy organs, and higher incomes are increasing the ability of patients to pay the copayments or insurance premiums that may be imposed. Public awareness of the availability and increasing success rate of organ transplantation is bound to grow. Provider groups, animated by an altruistic con-

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24. See Wildavsky (1988) for a discussion of the increasing importance of intergroup competition in the budgetary politics of the 1980s.

25. As of 31 March 1988, there were 848 individuals waiting for hearts (almost double the number of a year earlier), 458 waiting for livers, and 12,751 waiting for kidneys. Needless to say, waiting lists are inadequate indices of potential demand; many individuals who want transplants are not even placed on lists because of the severe shortages. Even these numbers, however, are quite large relative to the number of transplants actually performed during 1986: 1,368 hearts; 924 livers; 8,976 kidneys; 45 heart/lungs; and 140 pancreata. (Telephone conversation with John Gold, Office of Organ Transplantation, U.S. Public Health Service.)

26. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9318.

27. The Uniform Anatomical Gift Act provides that "an individual who has sustained either irreversible cessation of circulatory and respiratory function, or irreversible cessation of all functions of the entire brain, including the brain stem, is dead." In April 1986, the DHHS task force report on organ transplantation indicated that 43 states had adopted the act.

28. 42 U.S.C. § 274 (1982).

29. See, e.g., Brody (1988); New York Times (1988) (first cancer patient to receive bone marrow transplant through computerized national register).

30. Another, more speculative possibility for increasing supply is to strengthen donor incentives by permitting a limited, regulated market in organs (Hansmann 1989).

cern for those who need organs as well as by a concern for their own incomes and professional status, will press for more transplantation and for increased third-party payments to cover the costs, which will in turn further spur demand.

Over time, these developments will generate pressures to relax the rigor of whatever allocative standards are being used. The evolution of patient selection criteria for kidney dialysis under the ESRD program is perhaps the closest model, and it is an instructive and in some ways a disturbing one. The history of the dialysis program chronicles a steady movement toward lowered selection standards and virtually universal access.[31] The fact that the fastest-growing dialysis population in the program since 1981 has been individuals over 75 years of age, for whom the prospects of successful treatment are relatively low, is only the most recent example of this dynamic. If past is prologue, patients now considered only marginal (or even unsuitable) candidates for organ transplants will gradually be permitted to qualify for federally subsidized care.

A number of technological advances are also likely to increase both supply and demand for organ transplants. Better histocompatibility techniques, longer preservation of organs, and more effective immunosuppressant drugs and aftercare have already raised the transplant success rate dramatically. There is every reason to believe that further gains in these areas will be forthcoming. Perhaps the most far-reaching innovation that would increase supply and demand would be the widespread use of xenografts (especially from monkeys and dogs) and the invention of usable artificial organs. Advances in these areas are probably only a matter of time.[32]

These supply, demand, and technological factors are not exogenous to the system of governmental payment. Indeed, payment policy directly shapes each of them. And to the extent that these factors have significant expenditure-increasing implications, we will have to rethink the bases for our existing commitments and decide difficult questions of resource allocation and public responsibility. To do that, we must recur to first principles concerning the role of government and apply those principles to the particular issue of government payment for organ transplants.

Why should government subsidize organ transplants at all? There are at least three possible justifications: efficiency, equity, and communitarian values. The

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31. See Wildavsky (1988). Despite the relevance of the ESRD experience, this movement toward coverage for more marginal patients whose survival prospects are relatively poor apparently has not yet occurred in the case of kidney transplants and may develop more slowly than in the case of hearts, livers, and other organs. First, there already exists a large pool of potential kidney transplant recipients who are young and are now on dialysis but whose prospects for successful transplants are relatively great. Second, success rates for kidney transplants are steadily improving. (Telephone conversation with Paul Eggers, 1 June 1988).

32. The federal government's decision in May 1988 to terminate funding for artificial hearts was quickly reversed as a result of congressional pressure, principally from senators Ted Kennedy and Orrin Hatch (Boffey 1988). This may bode well for the prospect of governmental support for the development of these devices and their counterparts for other organs.

efficiency argument for government payment is based on a claim that an organ transplant is a merit good. The essential idea is that society in general, not just the organ recipient, derives benefit from a transplant. Although the precise nature of this external benefit is not completely clear, it seems to consist of some kind of psychological identification of the healthy with the ill. This empathy may rest on a widespread sense that "there but for the grace of God go I" or on a more instrumental wish that by helping another one can assure that one will be helped when one's own turn with catastrophe comes.

Whatever the source of these external benefits, they could support an efficiency argument for public subsidy in two ways. First, the private consumption decisions of potential recipients would in that event not yield "enough" transplants to satisfy the preferences of the rest of us; government intervention would be necessary to produce the right number. Second, organ transplants could be subject to free-rider effects on the supply side—that is, private developers of the complex technology might be unable to fully appropriate the benefits that their investments generate because others can use that technology without sharing in the costs of developing it. Again, it would follow from this claim that private investment in such technology would be suboptimal without government subsidy.

The equity justification is rooted in egalitarian values. Because advocates seldom articulate their assumptions about equality, however, the equity argument is not easy to elaborate. Most commentators do not spell out, much less justify, their views concerning the particular ways in which people are (or should be treated as) equal with respect to organs. For example, they fail to distinguish between equity in supplying organs, equity in distributing them, and equity in using those that we already have but may not need (e.g., our second kidney). Nor do they often address the tradeoffs between efficiency and equity in the supply and allocation of organs, or consider the other values implicated by moves toward greater equality.

In its common form, however, the equity argument makes two kinds of claims. First, it maintains that all individuals should have an equal, or at least an adequate, opportunity to extend their lives, regardless of their wealth or access to private insurance.[33] Government payment for organ transplants is a way to ensure this equal or adequate access. The second claim maintains that like cases should be treated alike, and that there is therefore no justification for denying government payment for organ transplants since it routinely pays for other, arguably less "medically necessary" services under Medicare and Medicaid. With the advent of a catastrophic health care program going well beyond ESRD, this "equal treatment" claim becomes even stronger.

Finally, there is a set of communitarian arguments for government intervention and subsidy. These range from absolutist arguments, which hold that the values

33. For a more general and comprehensive consideration of the issue of equality and adequacy of health care, see President's Commission (1983).

of social benevolence and solidarity demand that the government act to save any life (especially a palpable, identifiable one) that its intervention might readily preserve, to more relativistic arguments, which merely contend that these values deserve more weight in the development of transplantation policy. In any form, however, a communitarian argument emphasizes our common vulnerability to the randomness of life-threatening disease and the mutual stakes, commitments, and obligations implied by our common, interdependent social life. This argument presupposes that there exists a moral community in which these mutual understandings and undertakings are widely shared and normatively accepted. In the communitarian view, the question of whether or not individuals who need an organ transplant can afford it or are insured for it becomes largely irrelevant. As members of the community, they begin with an equal moral claim to the organ, just as they have an equal obligation to support (presumably through taxes) the like claims of others.[34] Organs, in this view, constitute "a community resource to be used for the good of the community as the community decides."[35]

For each of these arguments favoring government subsidy for organ transplants, there is a corresponding set of arguments against such subsidies. Thus it can be argued that efficiency is actually ill-served by subsidy. In this view, transplants are not really merit goods because virtually all of the benefits from transplants are reaped by the organ recipients and their families, while the external benefits are slight in comparison. Thus an efficient allocation of resources would be attained by making recipients pay for the benefits they receive. The free-rider claim can also be disputed on the ground that although it might justify government support for research on transplantation, it would not follow from that support that government should subsidize either organ procurement or the medical services required for transplantation, both of which can readily be priced in the market.

Even if the efficiency argument were thought to justify some government efforts to influence the distribution of organs, the present system might be vulnerable to criticism. Efficiency considerations, for example, would not justify subsidizing recipients of transplants generally; rather, they would suggest limiting the subsidy to the smaller set of transplants that are likely to achieve the efficiency purpose of the subsidy. The subsidy might target, for example, those transplants that involve

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34. Although not characterized as such, these are the premises that seem to underlie the task force report on organ transplantation (Task Force 1986). It should be emphasized that in the communitarian view the claims referred to in the text are only equal a priori. This view is wholly consistent with a community applying restrictive criteria to allocate the limited number of organs, although it might well rule out particular allocative criteria. Similarly, this view does not necessarily require equal tax rates regardless of ability to pay, but it would constrain the kinds of arguments that could justify unequal tax rates.

35. Robertson's (1987) observation is limited to what he sees as a trend toward viewing donated organs in this way, but it may be but a small step toward extending this view more generally to all organs and tissues. See, e.g., Reinhold (1988) (lawsuit involving issue of whether patient retains rights to his "waste" blood and tissue in face of needs of medical research).

truly innovative techniques. It might also favor those that produce other positive externalities that the unregulated market would not internalize. This last approach cold have some interesting, and possibly perverse, results. Thus, it might justify subsidies for precisely those individuals whose transplants, being "mediagenic" in the sense described earlier, would generate the most satisfaction among the general public even if they failed to meet other, arguably more rational criteria.

The equity and communitarian arguments for subsidy can also be countered. Even if it is true that people should have equal or (in the more common formulation) adequate access to "medically necessary" life-saving organ transplants, it is also true that the level of resources necessary to vindicate this equitable principle would be staggering and that using them in this way would create additional and perhaps greater inequities. Several years ago, the federal government estimated the cost range of organ transplants at $57,000–$110,000 per heart, $135,000–$238,000 per liver, $25,000–$30,000 per kidney, and $30,000–$40,000 per pancreas.[36] To devote these resources to transplants is to jeopardize other efforts to increase social equality, efforts that may be far more compelling.

When society refuses to tax itself to provide these resources, it reveals the fact that it does not really accept, or at least is not prepared to act upon, that conception of equity. It may be true (as the public choice analysts remind us) that social decisions of this kind do not fully represent individual voters' true preferences about organ distribution. Still, these resource decisions are probably the most reliable evidence we have about the distributional pattern that society prefers.

Communitarian arguments can be met in several ways. First, one may challenge the empirical and normative premises of the communitarian view. Thus one might deny that any moral consensus exists concerning either the obligation to share organs with strangers or the distributive criteria that should apply. One might insist instead that society regards, and ought to regard, such questions as matters for individual rather than political choice. And even if society values communal solidarity, it may regard paying for organs as a poor way to secure that value. For government to provide an organ transplant to everyone who would want one (even—or perhaps especially—if we assume that the supply of organs were less constrained than it is now)[37] would prevent society from devoting those resources to other things such as education, infrastructure, welfare reform, defense, cigarettes, and other forms of public and private consumption that the community evidently values more highly. Public payment for organs could also require a tax rate and administrative apparatus entailing significant wealth losses for society.[38] Es-

36. See Task Force (1986). The cost of transplants may well have increased since then.

37. In the absence of technological breakthroughs, the constraint in supply is likely to continue. Indeed, if seat belt and helmet laws are observed and other public safety measures are successfully established, the supply of transplantable organs may well decrease, other things remaining equal.

38. In this connection, Hansmann (1989) has provocatively suggested that society may have contrived *not* to solve the organ supply problem and thus the equity problem precisely because it fears the allocative consequences that would occur if it did so.

pecially at a time when the budget deficit is a central social and political issue, the communitarian argument for this particular subsidy is unpersuasive. Instead, the argument simply begs the difficult question of social priorities, a question to which I now turn.

Principles for government payment policy

If we are prepared to assume that nonexperimental organ transplants should be publicly subsidized and should not be subject to any real fiscal constraints (other than those contained in the applicable DRG and other regulations), then the only significant limitation on the government's commitment would be the available supply of transplantable organs. Even that constraint, of course, would be relaxed to the extent that the government is willing to spend money in an effort to increase that supply.

We must assume that at some point, the public will want to impose some limits. However, it is not clear that the current or even the projected expenditures for organ transplants are approaching that point. Nonetheless, it is not too soon to begin searching for principles and criteria capable of restricting the public's commitment to the resources realistically available for its fulfillment.

These principles and criteria are necessary to resolve the central policy issues relevant to government payment for organ transplants. Five are especially important: eligibility, comprehensiveness of benefits, reimbursement formulas, entitlement, and level of government. I do not mean to suggest that these are the only issues or that I can supply the needed principles and criteria. My intention is only to indicate what some of the relevant questions are and how they might be approached.

Eligibility. Which individuals should be covered by government-funded organ transplant benefits? In one sense, the question might seem irrelevant. After all, under Medicare and Medicaid (and most private health insurance policies), the standard criterion of eligibility is "medical necessity," and a new organ doubtless is "medically necessary" for most (if not all) nonrenal transplant candidates. But given limited resources for organ transplants, this broad eligibility creates an obvious policy and fiscal dilemma. Until now, the dilemma has been defined out of existence by characterizing nonrenal organ transplantation as "experimental," but this strategy of avoidance cannot serve indefinitely; indeed, as the government's compromise approach to funding heart transplants suggests, the strategy has already become a transparent, if understandable, expedient by which the government hopes to maintain fiscal control over a potentially open-ended commitment.[39]

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39. An alternative approach would be for the government to adopt an explicit cost/benefit definition of "medically necessary" or to abandon that standard altogether (Havighurst and Blumstein 1975).

In any event, whatever the difficulties in defining moral desert or social need, it would be hard to make the case that the groups that are now covered[40]—the elderly, the disabled, anyone with ESRD (under Medicare), and low-income people (under Medicaid in those states whose programs provide such benefits)—have the most compelling claims to receive this precious advantage. As individuals, many of them (especially the poor) would presumably qualify under any reasonable need-based criteria. But the fact that the legal right to government-subsidized organ transplants is so categorical testifies more to the political influence of the covered groups and the programs and institutions that serve them than to anything else.

Because individual or group eligibility for organ transplant benefits will inevitably depend on the fiscal resources that are available for them, a central issue is whether those resources should be expanded, contracted, or stabilized at current levels. That question, of course, cannot prudently be answered in the abstract; it depends upon competing social claims and the larger programmatic structure in which organ transplantation activity is to be embedded. But it is most unlikely that the federal government and many states will decide to spend less on transplants than they are now spending,[41] and the experience with expenditures under the ESRD program suggests that the status quo is probably not stable.

The real issue, then, is how much more governments will spend, and on whom. In thinking about these questions, two assumptions seem plausible. First, a universal health insurance program at the national level[42] will not be politically or fiscally acceptable for some time. Second, additional expenditures on organ transplants will follow the incremental, group-by-group approach that has traditionally been taken in the health field. For political and programmatic reasons, and because allocation decisions on individual moral or need-based grounds are so difficult in this area, governments will expand eligibility to new categories of people rather than to those individuals, regardless of group membership, who are able to satisfy some need-based criteria.

If this categorical approach to expanding eligibility for organ transplants is taken, children—both the poor who are not now covered by Medicaid and the nonpoor—would seem to be the logical next step.[43] Covering this group would not only tend to maximize the marginal benefits of organ transplant expenditures by extending them to those with the longest expected lives; it would also accord

40. Eligibility for such persons is limited only by clinical patient selection criteria adopted by providers under broad federal guidelines. In the case of heart transplants paid for by Medicare, the facility must also be approved by DHHS.

41. See, for example, Oregon's apparently unsuccessful effort to do so (Wildavsky 1988).

42. In this regard, the experience with Massachusetts's new program of comprehensive health insurance will be important.

43. See 10 U.S.C. § 1079K (1982), a 1984 amendment that added coverage under the CHAMPUS program of liver transplants for the dependents of active duty members of the armed forces, and was originally limited to dependents under the age of 18. (Telephone conversation with Myron Genel, 10 June 1988).

with widespread social norms concerning both the use of age as a criterion for social benefits in general (see Schuck 1979) and the special claims of children in particular. It is thus all the more striking that Congress has recently decided to allocate the marginal transplant dollar to those groups which are already preferred. By enacting a catastrophic health insurance program under Medicare, a significant diversion of resources away from children and toward the elderly seems quite likely.[44]

On more general issues of eligibility, organ transplant policymakers must not forget in practice what is so obviously true in principle—that transplants (to the extent that they remain scarce) must somehow be allocated among competing claimants. The allocations may be based on bright-line rules (such as age or number of dependent children) or on criteria that involve more or less discretion in their application (such as quality of life). The eligibility criteria may be established by providers, payers, or some other decisionmaker.[45] Alternatively, allocations may be based on the claimants' ability to pay in the market or on queuing. But in this area, "tragic choices" (as Calabresi and Bobbitt 1978 have called them) cannot be avoided.

Each of these allocative methods has distinct advantages, but each is also undeniably arbitrary—even cruel—in its own way. Because the goals of equity, efficiency, and administrability of the allocational scheme inevitably conflict, some combination of these methods probably will be superior to any single one of them. It might be desirable, for example, to allow some proportion of the available organs to be traded in a regulated market (thereby inducing a larger supply) while reserving the others for more centralized allocation[46] (thereby ensuring some access for low-income, uninsured people or others who are deemed especially deserving[47]). But in the absence of some dramatic technological breakthrough, the necessity to choose will become increasingly urgent.

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44. Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 100-360. Although final implementing regulations will not be issued for some time, several features of the new program seem reasonably clear. Even if it does not pay for transplanting any organs that are not now covered by Medicare, it will presumably pay for a larger portion of the cost of those transplants that Medicare does cover. At the very least, the new program, beginning in 1990, will pay for immunosuppressive drugs beyond the one-year post-transplant period for which payment is limited under current law, although some copayments will be required. *Id.* at Section 202. Dialysis patients, who are now subject to copay 20 percent of the cost for each session, will be even greater beneficiaries of the new catastrophic coverage.

45. These criteria might involve various formulations of "need," such as medical, expected life-years, or family responsibilities. They might instead employ randomizing methods, which eschew such awesome and inevitably arbitrary determinations.

46. The issue of just how centralized the allocation must be is a separate but related policy question, which I discuss below in the section on level of government.

47. Needless to say, such an approach would be highly controversial and would have to be very carefully designed. The Hill-Burton program, which required hospitals that had received federal construction grants and loans to allocate a certain level of services for patients unable to pay, provides one possible model for such a policy, although this, too, has been quite controversial (Blumstein 1986).

Comprehensiveness of benefits. Assuming that an individual is eligible for organ transplant benefits, how comprehensive should those benefits be? In particular, should they cover all organs? Should they cover tissues as well as organs? Should they include limits on immunosuppressant drug and aftercare benefits?

Any governmental policy on benefits and payment, like any policy on eligibility, will be shaped largely by fiscal, political, and programmatic considerations. But within any given set of such constraints, the benefit structure should also be designed with certain other policy goals in mind. For example, it should accelerate (or at least not impede) the emergence of new, superior, cost-effective technologies (e.g., artificial organs) and delivery systems that can improve on current organ transplant methods, rather than entrenching the status quo through government payment policies.[48] And wherever possible, regulators should adopt benefit standards that emphasize a provider's performance rather than its inputs or processes, thereby increasing the actual effectiveness of the program.

Another benefits-related issue is how organ transplants should be financed. A strong case can be made that such benefits, or some portion of them, should ordinarily be given in the form of loans, with outright grants perhaps being reserved for low-income recipients. Organ transplants (especially for nonelderly patients) should be viewed as a current investment that is cheaper and more satisfying than even life-sustaining alternatives (e.g., kidney dialysis) and that thus yields a stream of future private benefits (income and quality of life) to the recipients and their families and friends. A share of those private benefits—perhaps calibrated according to an age- or income-related sliding scale—arguably should be returned to the public whose investment made them possible.

I hasten to add that this rationale for using loans rather than grants to finance most or all of these procedures, at least for those who can afford them, extends well beyond organ transplants to other goods whose costs are large but readily divisible and whose benefits flow over time and mainly accrue to the individuals (and their families) who consume them. Organ transplants are by no means unique in possessing these features; higher education and housing loan programs at the federal and state levels are more familiar analogues.

The implementation of this approach for organs, of course, would need to be carefully fleshed out; as always, God is in the details. But in general, it would seem to have several important advantages. It would serve equity goals by enabling a larger number of needy individuals to benefit from transplants. It would serve efficiency goals by no longer treating scarce organs as if they were free goods.

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48. In this regard, the ESRD program's earlier policy of reimbursing for center-based therapy, 42 C.F.R. § 405 (1987) (now redesignated as Part 413), but not for the cheaper but no less effective home dialysis, is a cautionary tale. This bias was eliminated by a 1978 amendment, Pub. L. No. 95-292, to what is now 42 U.S.C. §§ 139(5)(j) and 1395(r)(r) (1982).

And it would serve communitarian goals by emphasizing the reciprocity of individuals' claims against and obligations to the society as a whole.

Reimbursement formulas. Organ transplant providers are currently reimbursed on the basis of the "reasonable cost" of organ acquisition, a DRG applicable to transplant-related services, and the "reasonable cost" of immunosuppressive drugs. "Reasonable charges" for outpatient aftercare are reimbursable under Medicare, Part B. These reimbursement formulas should be carefully and periodically reviewed in an effort to encourage greater efficiency. For example, the development of DRGs for physician charges, better patient cost-sharing formulas, and improved drug procurement techniques may be possible and desirable.

Entitlement. Once an individual's eligibility for an organ transplant has been determined, should that individual be entitled to those benefits? Or should those who administer the program instead allocate them to eligible individuals on a discretionary basis depending on the program's budget, the number of potential beneficiaries in the queue, or other factors?

As a lifesaving benefit, the arguments in favor of treating organ transplantation as an entitlement are obviously strong; we do not like to subject people's survival to the discretion of bureaucrats. And to the extent that organ transplants, like ESRD benefits more generally, are treated as entitlements under existing programs (Medicare, Medicaid, the VA, and CHAMPUS), it will be difficult to treat those benefits differently than other program benefits.[49]

On the other hand, there surely would—and should—be strong political resistance to creating another "uncontrollable" program, especially one with enormous budgetary implications, at a time of concern over large federal deficits.[50] In this respect, the government's experience with the black lung and ESRD entitlement programs has been profoundly disturbing.[51] The political interests that surround these programs (especially ones like ESRD, which has powerful provider as well as recipient constituencies), make it extremely difficult to limit eligibility and benefit levels once they are in place; one can easily predict that organ transplantation, with its influential medical centers, mediagenic recipients, and flamboyant technology, would be particularly resistant to change.

Moreover, it is not at all clear that if we decided to create a new entitlement, organ transplantation would be the service of choice. Even when we count as benefits the feelings of gratification and solidarity that society evidently derives from

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49. As noted earlier, the normative groundwork for an entitlement approach has been laid by the report of the President's Commission (1983) and by the Hill-Burton program. See Blumstein (1986).

50. Indeed, Section 401 of the Congressional Budget and Impoundment Control Act of 1974, 31 U.S.C. § 1351 (1982), establishes special notice and procedural requirements that must be met before new entitlements may be created.

51. See Wildavsky (1988: 309–24) for an account of the unanticipated growth of these entitlements.

providing transplants to the most mediagenic candidates, the benefit/cost ratios of, say, expanded child health or prenatal care programs are likely to be much higher. And this does not even address the comparative social merits of spending those resources on health-related activities, such as research on safe cigarettes or alcoholism prevention, or of nonhealth needs, such as housing for the homeless or job training for the poor. These plausible alternatives suggest that at the very least, specific benefit/cost comparisons of organ transplants to other forms of public intervention should claim a high priority for future policy research before the government commits itself to large additional expenditures on organ transplantation.

Level of government. Assuming that organ transplants are to be financed by government, a decision must be made as to whether the funding source should be the federal government, the state governments, or both. The arguments for federal payment are obvious: the traffic in organs is national in scope; there are surely economies of scale in certain aspects of organ transplantation (e.g., procurement networking, research, diffusion of technology, etc.); and the federal government is already funding the vast majority of organ transplants. In addition, the high stakes in organ transplants and the willingness of desperate patients to move anywhere in order to obtain them suggest that diversity among the states with regard to benefits might be more problematic here than in many other policy areas in which state programmatic diversity prevails. On the other hand, many states are, at least for the present, more fiscally sound than the federal government, and the states are already funding more nonrenal organ transplants through their Medicaid programs than the federal government is.

Moreover, the connection between who pays the bill and who makes the allocation decisions and administers benefits is neither a logical nor a politically necessary one, and there are plausible arguments in favor of severing it in the case of organ transplants. Indeed, if organ transplant decisions involve "tragic choices" to ration (Calabresi and Bobbitt 1978; Aaron and Schwartz 1984; Blumstein 1981; Schuck 1981), perhaps they should not be made at the federal level but should instead devolve to regional, state, or local authorities. There is simply no basis for assuming, as the federal government now does,[52] that the criteria for allocating organs ought to be the same everywhere. Indeed, we should expect that communities with very different demographic configurations and social norms might wish to make quite different choices about priorities and distribution.[53]

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52. See United Network of Organ Sharing (UNOS) policies (31 May 1988), sections 3.5, 3.6, and 3.7. For a general critique of the kind of due process model that UNOS adopts, see Havighurst, Blumstein, and Bovbjerg (1976).

53. The problem of powerful incentives to move from one state to another depending upon these policy differences would have to be faced, of course, and might in the end militate against this devolutionary approach.

Whether or not the federal government continues to fund almost all organ transplants, therefore, the precise role of lower levels of government remains an open question. Under a revenue-sharing or Title XX model, for example, the federal government could provide those funds in the form of lump-sum payments to the states (subject to some federal standards) with the states deciding how to allocate them among potential organ transplant recipients. Many other hybrid forms are possible.

The existing concentration of transplantation activity (especially with regard to hearts and livers) in certain medical centers raises a further question: by encouraging regional consortia of transplant providers through federal/state cost sharing, can the federal government improve quality of care and achieve economies of scale through a greater emphasis on high-volume practice and functional specialization? Unfortunately, preliminary research provides reasons for skepticism about the benefits, and also raises concerns that greater centralization could stifle innovation and increase costs (Sloan, Shayne and Doyle 1988).

Conclusion

Government's growing fiscal commitment to organ transplants warrants close scrutiny for reasons that go well beyond the technology, costs, and benefits of these procedures. Although much public commentary seems to view them as unique, most of the moral and policy problems they present are quite familiar; indeed, their uniqueness, such as it is, will diminish over time as more organs become available for transplant. If most transplants today involve vital organs that preserve life, they may someday be available simply to improve it. If the effectiveness of these procedures increases but their costs do not, they will come to be regarded as ordinary rather than exotic care and the political pressures for making them as routinely available as artificial limbs (or dental bridges) may grow. If they now require a donor, with all the moral and practical obstacles that entails, technological and policy innovations may succeed in removing that constraint as well.

With these changes, transplants will come to resemble the many other good things that individuals very much want and which they hope to get others to pay for through the medium of government. When that occurs, the very commonness of transplants may deprive them of their dramatic, mediagenic character, while their greater availability will increase the fiscal stakes to the public. The existing political advantage of transplants will diminish along with their distinctiveness, and they will have to compete with other valued goods on more equal terms. Government payment policy should welcome and nurture this heightened competition.

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The Politics of Organ Transplantation: A Parable of Our Time

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Abstract. This paper reviews the historical development of federal government policy for kidney, heart, and liver transplantation. It examines several political dimensions of whole organ transplantation: the role of the print and broadcast media; the management of organ procurement; the certification of transplant centers; the evaluation of new surgical procedures; and the issues of financing, distributive justice, and rationing of scarce medical resources. The author finds that the media, though powerful in affecting transplant policy, have not been subjected to critical analysis. Organ procurement modifications, driven by a need orientation toward closing the gap between actual and desired levels of performance, may have adversely affected performance. The case of liver transplantation suggests the need for improved institutions and mechanisms for evaluating new surgical procedures. Finally, states that confront the need to meet a binding budget-balancing requirement may allocate funds away from expensive medical procedures that benefit the few toward basic services that benefit the many; the Oregon and Virginia Medicaid programs exemplify this point.

Introduction

Organ transplantation represents a medical and social phenomenon of modest scale. Fewer than 12,000 kidney, heart, and liver transplants were performed in 1987, hardly a large number. Although these procedures are costly, the aggregate cost is limited by the scarcity of donor organs. Whether the total number of procedures will double by the end of the century is an arguable question. Why, then, does an effort of such modest proportion drive so much commentary and controversy?

Organ transplantation, as Englehardt (1985) noted, encompasses not one but several controversies. New developments continuously extend clinical capabilities and stretch fundamental community norms. These developments include new definitions of when death occurs, the legal and ethical bases for organ donation, the ownership of organs and bodies, the relation of the state to the individual, and the role of governments and markets. Transplant procedures represent new therapeutic opportunities that flow

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The views expressed in this paper are those of the author and do not represent those of the Institute of Medicine or the National Academy of Sciences.

from advances in medical science; they are lifesaving, but limited by physical and financial scarcity; and they raise questions of equity at the level of distribution of organs and of allocation of public resources. These issues, not the magnitude of the effort, give significance to organ transplantation.

The politics of this domain constitute a contemporary parable. Thus in the first part of this paper I will present a historical overview of the evolution of federal government policy toward kidney, heart, and liver transplantation. For each procedure, I will consider three types of policies: status, coverage, and reimbursement; organ acquisition and distribution; and facility certification.[1] ("Status" refers to whether a procedure is experimental or accepted treatment; it is a criterion for making coverage and reimbursement decisions. See Fox and Swazey 1974; Rettig 1987). In the second section I will address several political aspects of transplantation policy in the 1980s, and I will conclude by drawing some lessons from this account in order to illuminate some salient policy issues.

Overview of organ transplantation policy

Much of the current organ transplantation system grew out of the institutions that evolved for kidney transplantation. Until 1982, these institutions—transplant centers, organ procurement agencies, and tissue-typing laboratories—developed in a largely apolitical environment. The issues were addressed quietly, with little controversy, and resolved on basically clinical grounds. Since then, however, the transplant system has become deeply involved in politics, and this is likely to continue for some time to come.

The 1970s were not a buoyant time for the transplantation field, which was then dominated by kidney transplantation. For example, in 1976, Terasaki showed that patient survival for kidney transplant recipients had gone up in the previous five years but that graft survival had actually declined by 1–2 percent per year since 1969 (Terasaki 1976).[2] Williams (1979) expressed a pessimistic view about the recent experience of kidney transplantation and its immediate prospects. Thus the nephrology and transplant communities greeted the introduction of cyclosporine[3]

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1. Biomedical research (the province of the National Institutes of Health) and the approval of new immunosuppressive drugs (the domain of the Food and Drug Administration), although important, are not addressed in this paper. Also not considered are corneal transplantation, which is very effective but not lifesaving and raises few fundamental questions (AMA 1988); lung and heart/lung transplantation, which remain experimental and infrequently performed (Toronto Lung Transplant Group 1988; Baldwin 1988; Penketh et al. 1987); pancreatic transplantation, an elective procedure whose effectiveness has yet to be demonstrated persuasively (Ramsay et al. 1988); and bone marrow transplantation, a procedure involving a renewable tissue and one of currently limited effectiveness.

2. Terasaki (1983) subsequently documented improvements from 1977 to 1981.

3. Cyclosporine was discovered accidentally by Dr. Jean Borel of Sandoz, Inc., in Basel, Switzerland, who returned from a trip to Norway with a soil sample that had been collected routinely. Upon testing, the sample was found to contain a fungus that turned out to have remarkable immunosuppressive properties.

with some skepticism, which was reinforced by the nephrotoxic effects of cyclosporine (these were subsequently found to be dose-related). Hopes had been raised and dashed too many times before.

Cyclosporine was introduced into clinical trials in the United States in 1980. Kidney transplantation trials were initiated at the Brigham and Women's Hospital, Harvard Medical School, the University of Minnesota School of Medicine, the University of California at San Francisco, and the University of Texas Health Science Center at Houston;[4] trials at Ohio State University subsequently followed. Heart transplantation work using cyclosporine was begun at Stanford, and liver transplant trials were initiated at the University of Pittsburgh and the University of Minnesota.

The clinical experience of transplantation was altered markedly by the introduction of cyclosporine into general use. For kidney, heart, and liver transplants, better graft survival outcomes were achieved, fewer rejection episodes occurred, and hospitalization was reduced. Professional attitudes were reshaped: pessimism yielded to genuine hope. A "new era" of transplantation was hailed (Aroesty and Rettig 1984).

Despite the success of cyclosporine, many kidney transplant patients expressed reluctance to incur large expenses for it because it was administered as an outpatient drug and thus not reimbursed by Medicare. Surgeons were confronted with patients who, for financial reasons, were resisting an immunosuppressive regimen that they wished to prescribe. This growing divergence between financial and clinical considerations drove the relatively passive transplant surgeons into politics—forever.

Kidneys and the transplantation infrastructure. Federal policy toward kidney transplantation resulted in the infrastructure of today's transplant system. That policy is summarized in the narrative that follows.

Kidney transplantation, first performed in Springfield, Massachusetts, in 1951, was developed in Boston in the 1950s and, with the discovery of immunosuppressive drugs, emerged as a therapy for kidney failure in the 1960s. Its emergence was greatly assisted by the concurrent development of the artificial kidney, which permitted terminally ill but prospective transplant recipients to wait months and even years for a suitable donor organ. Donor sources included both closely matched living relatives and cadavers of recently deceased individuals.

The nearest thing to an official "endorsement" of kidney transplantation as an efficacious procedure came in 1967 with the issuance of the report of the Committee on Chronic Kidney Disease (also known as the Gottschalk Committee, after its chairman, Carl W. Gottschalk). The committee had been convened to advise

4. See the *American Journal of Kidney Disease*, vol. 6, no. 6, 1985, for papers from these five centers and the Canadian Multicenter Trial that were presented at a National Kidney Foundation conference on the impact of cyclosporine on clinical renal transplantation.

the Bureau of the Budget about emerging federal programs for treating kidney failure patients by dialysis, for which financing was the paramount consideration (Rettig 1981). Its report, submitted in September 1967 to the director of the Bureau of the Budget, Charles Schultze, stated that "transplantation and dialysis techniques are sufficiently perfected at present to warrant launching a national treatment program" and urged this course of action (Committee on Chronic Kidney Disease 1967; Rettig 1976).

Then, as now, federal policy toward kidney transplantation derived from a larger concern for the financial implications to the government of dialysis treatment for victims of permanent kidney failure (Eggers 1988). In the late 1960s, well before the enactment of the Medicare entitlement for chronic kidney failure, kidney transplantation was looked upon as a more effective and less costly substitute for hemodialysis. Consequently, in 1969, the Public Health Service (PHS), alarmed by the fiscal implications of both center and home dialysis, launched a transplantation program that included integrated home dialysis and transplantation centers, seven cadaver kidney procurement contracts,[5] and a contract with the University of California, Los Angeles, to maintain a computerized donor/recipient matching program for the western United States (Rettig 1982).

Thus, when Section 299I was included in the Social Security Amendments of 1972,[6] it established an entitlement for individuals who were "medically determined to have chronic renal disease," making no distinction between whether they needed hemodialysis or kidney transplantation (Rettig 1976). Consequently, the interim regulations[7] and the final rules[8] governing implementation of the end-stage renal disease (ESRD) program provided for the financing of organ acquisition, the transplant procedure, twelve months of posttransplant care, the return to dialysis (if necessary), and the certification of transplant centers (Rettig and Marks 1980).

In the ESRD interim and final regulations of 1973 and 1976, Medicare required that kidney transplant centers meet certain specific transplantation-related conditions of participation that went beyond the general conditions that all Medicare-participating hospitals had to meet. Although these requirements went largely unnoticed by many policymakers, they did provide a basis for selective coverage of subsequent procedures. Today, 184 hospitals are certified for kidney transplantation.

Initially, the large centers argued that only those facilities performing 50 procedures annually should receive unconditional certification; those performing 26 procedures a year would be eligible for conditional certification (Rettig and Marks

5. The institutions given contracts were Emory University; the Interhospital Organ Bank (Boston); the Medical College of Virginia; the Transplantation Society of Northeastern Ohio, Inc. (Cleveland); the University of California, Los Angeles; the University of California, San Francisco; and the University of Utah.

6. Pub. L. No. 92-603.

7. 38 Fed. Reg. 17,210 (1973).

8. 41 Fed. Reg. 22,502 (1976).

1980). This was unacceptable to clinicians, administrators, and politicians. Douglas Richard, the Atlanta regional representative of the Social Security Administration's Bureau of Health Insurance (BHI), wrote this note to Thomas Tierney, director of BHI: "If we go the 26/50 route, good ol' Georgia won't have no transplant center. Worse yet, there won't be any in the whole ——— region. And here I thought discrimination against the South was about gone!"

Subsequently, the proposed rules called for 25 procedures annually for unconditional certification and 15–24 for conditional approval. The final rule prescribed 15 procedures per year for unconditional approval and 7–14 for conditional certification. The story behind the shift in numbers was simple: first, the higher threshold would have resulted in an uneven regional distribution of transplant centers; second, the data failed to support a correlation between number of procedures and outcomes (Rettig and Marks 1980).

The organized acquisition and sharing of kidneys between transplant centers began with the PHS contracts of 1969. The Medical College of Virginia, one of the original contractors, worked out an organ-sharing arrangement in the early 1970s with the University of Virginia, Emory University, Duke University, Indiana University, and several other institutions. This arrangement became the basis for the establishment of the Southeast Organ Procurement Foundation (SEOPF) in 1976.

It was the Centers for Disease Control (CDC), however, that in 1976 initiated the analytical effort to improve the performance of the organ procurement system (Bart, Macon, Whittier et al. 1981; Bart, Macon, Humphries et al. 1981). The CDC group sought to apply the methods of epidemiology to organ donation and acquisition by focusing on the identification of hospitals in which the potential number of kidneys was greatest and on the processes of obtaining them. Pilot programs were initiated by the CDC in Atlanta and in Kansas City, Missouri. These efforts gathered strong support in the early 1980s.

In 1978, Congress enacted legislation to modify the incentives within the ESRD program to promote home dialysis and kidney transplantation. The period of entitlement for successful transplant recipients was extended from 12 to 36 months following transplantation. Congress did not consider the option of removing a time limitation for the transplant benefit in a program that continued the dialysis benefit until death. Interestingly enough, hearings pertaining to this legislation that began in 1976 and concluded in 1978 did not include testimony from one kidney transplant surgeon.

Indeed, transplant surgeons barely participated in the policy events of the 1970s, a decade that shaped much of their professional lives and livelihood. They left much of the work of defining ESRD policy to the nephrologists, instead devoting most of their effort to building local institutions and the cooperative relations among institutions—the transplant infrastructure—without much interference from the federal government.

Hearts and the evolution of transplantation policy. Federal policy toward heart transplantation built on the institutional infrastructure of kidney transplan-

tation and added its own unique imprint. In particular, no effective artificial heart permits prospective recipients to wait months, even years, for a transplant, nor are there any living related donors as there are with kidney transplantation. The policy developments are summarized in the following section.

In December 1967, Dr. Christiaan Barnard performed the world's first heart transplant in South Africa. The prospect of rapid, worldwide imitation so concerned the Board on Medicine of the National Academy of Sciences (predecessor to the Institute of Medicine) that it recommended in early 1968 that cardiac transplantation (which it described as "a scientific investigation and not as yet an accepted form of therapy") be performed only at those institutions having extensive laboratory experience (with animals), demonstrated surgical competence, and "a thorough understanding of the biological processes that threaten functional survival of the patient."[9]

Notwithstanding this warning, 105 transplants were performed in 1968, 26 in November alone. Mortality was unacceptably high. A 1974 study reported that of the 162 heart transplants performed through May 1970, 18 patients who had received transplants from 0 to 21 months earlier were still alive, but 144 were dead. Of those who had received transplants 0 to 3 months earlier, 3 patients were alive and 104 were dead (Fox and Swazey 1974). The Montreal Heart Institute announced in January 1969 that it was suspending cardiac transplants, and a worldwide moratorium was essentially invoked against further activity by the end of 1970.

During the moratorium Dr. Norman Shumway of Stanford University Medical Center continued to pursue the experimental challenge of heart transplantation. Through careful, steady research during the 1970s, he worked out many of the surgical aspects of heart transplantation as well as some of the immunosuppression problems related to graft preservation and the treatment of rejection; he also dealt with organ donation (Lancet 1980). Even so, one prominent clinician voiced a warning in 1978 about extending heart transplantation beyond "a few carefully selected patients with end-stage heart disease who otherwise would surely die soon" (Austen 1978).

In November 1979, HCFA began paying for heart transplants performed by Shumway at Stanford. It did so on an interim basis, following findings by the PHS about the safety and efficacy of the procedure at Stanford.[10] DHHS officials had discovered the previous year that Blue Cross of Northern California, the California Medicare intermediary, had paid for 23 transplants and 21 posttransplant cases at Stanford since 1973 on the assumption that the procedure was no longer experimental (Knox 1980). In early 1980, while DHHS officials reviewed the situation, an administrative law judge for the Social Security Administration ruled that Med-

9. National Academy of Sciences news release, 28 February 1968, Washington, DC.
10. 52 Fed. Reg. 10,935 (1987).

icare must pay a $30,534 claim for a Tucson, Arizona, resident who had received a heart transplant from Dr. Jack Copeland of the University of Arizona, one of Shumway's trainees. Blue Cross of Arizona, the local Medicare intermediary, had denied the reimbursement request on the grounds that the heart transplant procedure was still "experimental or investigational."

DHHS secretary Patricia Harris involved herself personally in the case. She was concerned that Medicare coverage of heart transplants would lead to program costs similar to those of the ESRD program. She also believed that patient selection criteria raised questions of "distributive justice." On 12 June 1980, Harris suspended the authority of the Health Care Financing Administration to pay for the procedure. In an announcement that may have represented the high-water mark of federal government support for technology assessment in medicine, Harris indicated that it was the intention of DHHS to require that Medicare coverage decisions be based not just on narrow safety and efficacy considerations but on documentation of cost-effectiveness, ethical implications, and long-term effects on society (Cohn 1980). Heart transplantation was to be the first procedure evaluated under this regimen.

As a result of Harris's decision, DHHS contracted with Battelle Memorial Institute in 1981 to perform the National Heart Transplantation Study. The five-volume report of that study was submitted to HCFA in the fall of 1984 (Evans 1984). The report estimated that using existing patient selection criteria, approximately 1,900 individuals would be acceptable candidates for heart transplants annually, and that perhaps 1,200 might be transplanted. First-year costs were estimated to be between $44.9 million (for 500 patients) and $116.9 million (for 1,300 patients). Survival was estimated to be 80 percent for the first year and over 50 percent for five years.

After reviewing the report for several months, HCFA released it to the public in May 1985 (Evans and Broida 1985). The principal investigator of the study, Dr. Roger Evans, had by that time been appointed a member of the National Organ Transplantation Task Force. His belief that heart transplantation was an effective therapeutic intervention, based on his lengthy and exhaustive study, found amplification through various channels, including the task force (Evans 1986).

On 17 October 1986, HCFA published a proposed notice regarding criteria for Medicare coverage of heart transplants. It read in part:

> This notice proposes Medicare coverage of heart transplantation under certain circumstances. We would extend coverage to heart transplants based on the results of the National Heart Transplant Study and our subsequent determination that heart transplants are a medically reasonable and necessary service when furnished by participating facilities that meet specific criteria, including patient selection criteria.[11]

11. 51 Fed. Reg. 37,164 (1986).

Heart transplants would be covered only if performed in centers "which demonstrate good patient outcomes," which included, but were not limited to, survival data.

Significantly, HCFA limited the beneficiaries to Medicare-eligible individuals. An approved facility "could seek Medicare payment from its Medicare intermediary for heart transplants performed *on Medicare patients*."[12] This restricted the eligible population to the elderly (who are generally ruled out on clinical grounds), the disabled, and those entitled because of end-stage renal disease. Indeed, HCFA had no statutory authority to do otherwise. Congress would have to enact an ESRD-type entitlement for HCFA to broaden eligibility, authority that the agency was disinclined to seek.

Applicant facilities, the notice also indicated, "must have an established cardiac transplantation program with documented evidence of 12 or more patients in each of the two preceding 12-month periods and 12 patients prior to that."[13] Such programs were "deemed to have the potential for acceptable data bases for estimating survival."[14] The regulations also stipulated a performance criterion in terms of patient outcomes: "Initially, the facility must demonstrate actuarial survival rates of 73 percent for one year and 65 percent for two years for patients who have had heart transplants at that facility."[15] In other words, serious applicant institutions must have demonstrated their commitment to heart transplantation in advance of application, their capability for tracking the results of their activity, and performance equal to that of Stanford.

On 6 April 1987 HCFA formally rescinded the 1980 ruling that had barred heart transplants from coverage as a medically reasonable and necessary service and adopted the coverage policy published the previous October.[16] In doing so, HCFA adopted a selective coverage policy that limited the heart transplant centers that could be certified for Medicare reimbursement to those with a specified level of experience and the ability to meet specified performance standards. It thus reversed a position taken in 1984, when it had opposed statutory authority for selective coverage that was provided for in an early draft of the transplant legislation. The reality forced on HCFA by heart transplantation was the need to move away from dichotomous, all-or-nothing coverage decisions by Medicare. Whether or not this decision was a precedent, it clearly marked a new policy for HCFA.

Livers and transplantation politics. Liver transplantation, although lagging behind kidney and heart transplants in number of procedures, ushered in the con-

12. *Id.* at 37,165 (emphasis added).
13. *Id.* at 37,166.
14. *Id.*
15. *Id.*
16. 52 Fed. Reg. 10,935 (1987).

temporary politics of organ transplantation. It did so by focusing on children rather than adults, in contrast to the European experience (NIH 1983a). Liver transplantation also became identified strongly in the public consciousness with several well-organized public relations campaigns for the donation of organs to particular children.

Liver transplantation was pioneered as a clinical procedure by the work of Dr. Thomas E. Starzl in the United States and Dr. Roy Calne in Cambridge, England (Starzl et al. 1982). Starzl attempted the first human liver transplant in 1963. Other groups in Boston and Paris followed in 1964. Results were so poor, however, that a moratorium was instituted for several years (Starzl et al. 1982; Markle and Chubin 1987). Starzl conducted 192 transplants from 1963 through 1980 while at the University of Colorado in Denver; in 1981, following a move to the University of Pittsburgh, he expanded his efforts substantially. The introduction of cyclosporine helped move the procedure forward.

In 1982, an infant girl from Bridgewater, Massachusetts, personified the drama of liver transplantation for the nation. Jamie Fiske faced certain death if she did not receive a liver transplant. Her father, Charles Fiske, led a highly publicized national campaign for a liver donor, including a direct appeal to the annual meeting of the American Academy of Pediatrics in October for help in finding a donor organ. His efforts succeeded: in November 1982, at age eleven months, Jamie was transplanted at the University of Minnesota, one of the country's premier transplantation centers. The Jamie Fiske success story received extensive national coverage in newspapers and on television and riveted the nation's attention on the natural scarcity of donor organs.

Publicity about Jamie Fiske and other children dying from terminal liver disease triggered responses within Congress and the executive branch. In Congress, Representative Albert Gore (D–TN), chairman of the Oversight Subcommittee of the House Science and Technology Committee, held hearings in April 1983 that led eventually to the enactment of the 1984 National Organ Transplant Act.[17] Although one kidney transplant recipient testified, the spotlight was on children who had received or who needed a liver transplant. On 13 April, the first day of the hearings, Billie Hall of Memphis made an emotional appeal for a donor liver for her terminally ill young son, Brandon. Shortly afterwards, Brandon received two liver transplants in quick succession, the second after the failure of the first. (Brandon died within a month.) The Fiske family—Charles, Marilyn, and daughter Jamie—appeared on the second day to support Gore's efforts. So did Captain John H. Broderick, U.S. Army, with his daughter Adrianne. CHAMPUS, the Department of Defense health insurance program, had refused to pay for a liver transplant for Adrianne on the grounds that the procedure was still experimental.

17. Hearings before the Subcommittee on Investigations and Oversight, 98th Cong., 1st Sess. (1983).

Gore strongly criticized DHHS for failing to declare that liver transplantation was no longer experimental. He deplored a recent decision by CHAMPUS to deny reimbursement for a liver transplant for Adrianne Broderick. Reflecting the views of many of his House colleagues, Gore expressed the belief that the forthcoming NIH consensus development conference on liver transplantation ought to concur with him and Dr. Starzl that the procedure was no longer experimental.

Gore opened the third and final day of hearings on 27 April by addressing two questions to the federal government witnesses:

> One, how does a new technology, such as liver transplants, go from being considered experimental and nonreimbursable to being efficacious and available to all, regardless of their ability to pay? Two, how can new life-saving techniques, which have been demonstrated to be effective yet may still be considered experimental, be made available to those in need who cannot afford to pay for them?[18]

Gore heard testimony from Assistant Secretary for Health Edward Brandt, Surgeon General C. Everett Koop, HCFA administrator Carolyn Davis, and Acting Assistant Secretary of Defense for Health Affairs John Beary. He then relentlessly pursued the witnesses about why the government still considered liver transplants to be experimental:

> What we have here is an absolutely absurd situation, and it is very frustrating. Most all the private insurance companies recognize that it [liver transplantation] is no longer an experimental procedure. Most of them are reimbursing for it.
>
> We have testimony showing that there is a 70- to 80-percent success rate with these procedures. We have testimony showing that it is cheaper to save their lives and go forward with the transplant than it is to pay for all the care needed during a lingering death, which you presently approve.
>
> And yet the government bureaucracies represented here absolutely refuse to recognize what is obvious to the medical experts in the field, and it is extremely frustrating. That is a slow, slow process that is cranking along toward the consensus conference in June, and then there will be an evaluation. It [the planning for the conference] has been going on for one year already. And, in the meantime, these children need the money, and in its place we have the, I think, bizarre spectacle of the Defense Department providing public relations guidance to mount public fundraising drives for the children of the military personnel that need these procedures to save their lives. There is something bizarre about that.[19]

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18. *Id.* at 498.
19. *Id.* at 572.

Gore, along with various other members of Congress, had found Dr. Starzl, who testified the first day, compelling regarding the effectiveness of the procedure.

A more probing examination of Gore's questions occurred after the second day of hearings. On ABC's "Nightline" on 14 April 1983, Ted Koppel devoted twenty minutes to organ transplantation. A three-way hook-up had Charles Fiske in the Washington, DC, ABC studio, Dr. Starzl at the Pittsburgh affiliate of the network, and the uniformed surgeon general at the Philadelphia affiliate.

Koppel focused on the central issue of when a procedure like liver transplantation ceased being experimental and became therapeutic.

> Koppel to Koop: "Why does it have to be that these [liver transplant] operations, which are clearly a last-ditch measure for these children, have to be regarded as experimental and not subject to government subsidy?"
>
> [Koop noted that planning had been going on for more than a year for a consensus development conference at the National Institutes of Health in the last week in June.]
>
> Koop: "It is quite possible that after that conference liver transplantation of certain types, of certain age patients, and of certain diagnoses might very well be declared nonexperimental but now therapeutic, and then it would be up to the Health Care Financing Administration to take the next step and perhaps cover liver transplants."
>
> Koppel: "Is there some statistical measure that is used, that once you get 60 percent, 70 percent, 80 percent it stops being experimental and becomes therapeutic?"
>
> Koop: "It doesn't depend upon a number. It will depend upon what is predicted as the future likelihood of this procedure."
>
> Koppel to Starzl: "Dr. Starzl, has it [liver transplantation] transcended experimentation?"
>
> Starzl: "Yes, I think it's a service [an established procedure]."
>
> Koppel: "How would you gauge that? How would you persuade someone who still needed to be persuaded?"
>
> Starzl: "Well, I'd bring in a few patients like that Fiske child and some of the other patients who were at the congressional hearings yesterday, and have them speak or just carry on their normal functions, and it's pretty obvious that they are normal."
>
> Koppel: "Forgive me. That's kind of begging the question. There are failures also and that's like my saying what if we turn to the failures. What objective measures can there be?"
>
> Starzl: "That would be my answer—people that have been restored to health. I think the fact that there are failures is probably irrelevant because there are failures in any form of therapy. What one looks at is that there can be stunning successes and in significant numbers."

> Koppel: "Let me try one more time. What I'm having trouble with is how one draws the line, because someone clearly is drawing the line between the therapeutic and the experimental. Where is that line to be drawn? No one seems to know."
>
> [Koop then suggested looking at Starzl's experience.]
>
> Koppel: "But he's not talking numbers. He's just saying talk to one of the successful patients."

Left unanswered by these exchanges was how to decide when a surgical procedure ceased being experimental.

The pressures of public opinion, congressional interest, and the leadership of DHHS led NIH to decide in 1982 to sponsor a consensus development conference the following year. The antecedents, processes, and outcome of that conference have been explored in detail by Markle and Chubin (1987). Briefly, the surgeon general, a pediatric surgeon, requested the conference as a means for clarifying the status of the liver transplantation procedure. NIH resisted, believing that the procedure was still experimental. But the surgeon general, with the support of Dr. Brandt, prevailed, and the decision to hold the meeting was reached.

As the time of the conference approached, attention was focused on it from various sources. The White House played a role, with President Reagan making and authorizing publicized appeals for particular children in need of organs and Michael Batten acting as the point man for pressuring state Medicaid directors to authorize payment for the procedure. Gore, as we have seen, used the legislative process to advocate for the desired outcome. Surgeon General Koop balanced conflicting roles as expert and advocate, and Dr. Starzl argued that the procedure was established.

The NIH conference was as much an effort at political lobbying for governmental approval of liver transplantation as it was a scientific assessment. The purpose of the advocates was to seek the NIH imprimatur that the procedure was no longer experimental. Once obtained, the target would become the HCFA coverage decision process; if the procedure was not experimental, HCFA had no basis for failing to designate it as a covered procedure. A favorable coverage decision by HCFA was relatively unimportant for Medicare coverage; few of the elderly, disabled, or end-stage renal disease beneficiaries were regarded as prospective liver transplant recipients. But a HCFA decision to cover the procedure was very important for state Medicaid agencies, for Blue Cross and Blue Shield plans, and for commercial health insurance firms. If HCFA designated the procedure as no longer experimental, these payers would have little choice but to follow.

Few data on outcomes existed at the time of the 1983 NIH consensus development conference. Four programs presented data on their experience—the University of Pittsburgh, Cambridge/King's College Hospital in England, Zentrum Chirurgie der Medizinischen Hochschule Hannover in West Germany, and the State University of Groningen of the Netherlands (NIH 1983a). Drs. Rolles and Calne of Cambridge

described their experience from 1968 through 1983: "Despite these evolutionary changes based on experience over the years, the perioperative mortality in the Cambridge/King's College Hospital series remains unacceptably high" (ibid.: 197). Pichlmayr, of West Germany, reported on experience with 71 liver transplant patients; only 26 were alive between one month and seven and one-half years. "It is well known," he said, "that the overall results in liver grafting have been poor in previous years and are still medium at present" (ibid.: 219). Kron, of the Netherlands, presented data on 26 orthotopic liver transplant patients: 16 were alive, 5 more than two years and 1 more than four years. But patient selection was done carefully; the 26 transplant recipients had been chosen from 210 referred patients.

Only Starzl presented data that might justify the claim that the procedure was effective. Of 170 patients transplanted from 1963 through 1979, only 33 percent had survived 12 months (NIH 1983a). But for 40 patients transplanted in 1980 and 1981 using cyclosporine, 28 (or 70 percent) were alive 12 months later (ibid.: 183–84). Such was the evidence for the effectiveness of the procedure.

The consensus panel acknowledged that the data were quite limited and issued a highly qualified statement of support. Regarding the more than 540 reported procedures worldwide, the report stated:

> Although extremely demanding and expensive, the operation has been shown to be technically feasible, and interpretable results have been reported from all four primary transplant centers. These clearly demonstrate that liver transplantation offers an alternative therapeutic approach which may prolong life in some patients suffering from severe liver disease that has progressed beyond the reach of currently available treatment and consequently carries a predictably poor prognosis. However, substantial questions remain regarding selection of patients who may benefit from liver transplantation; the stage of their liver disease at which transplantation should be performed; survival and clinical condition of patients beyond the initial year after transplantation; and overall long-range benefits and risks of transplantation in the management of specific liver diseases (NIH 1983b).

Consequently, according to the conference summary:

> Liver transplantation is a promising alternative to current therapy in the management of the late phase of several forms of serious liver disease. Candidates include children and adults suffering from irreversible liver injury who have exhausted alternative medical and surgical treatments and are approaching the terminal phase of their illness. In many forms of liver disease the precise indications and timing of liver transplantation remain uncertain or controversial (ibid.).

Weak as this conclusion was, it soon became the basis for a Medicare decision to cover the procedure on the grounds that it was no longer experimental. Subsequently, a number of advocates placed a great deal of importance on the state-

ment. The Pittsburgh team, for example, recently cited the report as evidence that "the procedure has finally gained acceptance as the preferred treatment for most forms of end-stage liver disease" (Gordon et al. 1987: 50).

President Reagan found the issue of small children needing the donation of a liver for transplantation so compelling that in his regular weekly radio broadcast on 23 July he appealed directly to the nation on behalf of a Texas girl, Ashley Bailey (Reagan 1983). "Today," he said, "I'm taking to the airwaves in hopes we can save one little eleven-month-old girl from Texas . . . Ashley Bailey. . . . What she needed then, and needs now, is a donor. Time is running out. I'm issuing a plea to the nation to find Ashley a donor. Once one is found, an Air Force jet is standing ready in case immediate, commercial transportation is not available."

Reagan also stated that a helicopter at Andrews Air Force Base, just outside Washington, DC, was ready to fly Candi Thomas, daughter of a White House electrician, to Pittsburgh if a donor could be found for her. The president noted that a conference called by the surgeon general at his direction had recommended the development of a public awareness program on organ donorship. He concluded with an appeal to the altruistic nature of the American people to support organ donation.

The White House, alert to the theatrical gesture, was willing to publicize individual cases but unwilling to consider additional financing for liver transplants. Ironically, having reduced federal support for the federal/state Medicaid program, the White House showed no compunction about twisting the arms of state Medicaid directors to ante up for such procedures.

In February 1984, following the NIH conference, HCFA decided to cover liver transplants for certain Medicare-eligible children (Lindsey and McGlynn 1988). Medicare beneficiaries are mainly those 65 years old or older, but also include those under 65 years of age who are disabled or have end-stage renal disease. Few children are eligible for the benefit. Medicare coverage for liver transplantation was limited to those with a clinical diagnosis of extrahepatic biliary atresia. In addition, the child must qualify for Medicare benefits under the disability insurance program; i.e., he would have to have worked, contributed to Social Security for a minimum of six quarters, and then lived another two years, unable to work because of his disability (ibid.). No procedures have yet been reimbursed under this provision. Federal government policy on liver transplants, therefore, stands in a somewhat awkward posture: because the procedure is no longer experimental, Medicare coverage was established, but in a manner that leaves the basic financing question largely unresolved.

General developments. The developments in kidney, heart and liver transplantation led to legislation in 1984 and a national organ transplantation task force in 1985–1986. The issues raised in the April 1983 Gore hearings were taken up by the Subcommittee on Health and Environment of the House Committee on Commerce and Energy, a legislation-writing committee. Bills passed by both

House and Senate became the basis for the National Organ Transplant Act of 1984, signed by President Reagan on 19 October.[20]

The 1984 statute created the Task Force on Organ Transplantation, authorized grants for organ procurement organizations, and directed the secretary of Health and Human Services to establish the national Organ Procurement and Transplantation Network (OPTN) to provide for the equitable and efficient allocation of organs, to establish a scientific registry of transplant recipients, and to report annually on the status of organ transplantation. Title III of the act prohibited the buying or selling of organs and established criminal sanctions for violations. Reflecting the pressure from patients and surgeons regarding cyclosporine, Congress also asked that the task force report on reimbursement for immunosuppressive drugs.

The task force convened in early 1985 and issued two reports in its eighteen-month existence. The first report, in October 1985, recommended Medicare financing for outpatient immunosuppressive drugs for transplant beneficiaries that was limited to "financially needy Medicare-eligible transplant patients" (Task Force 1985: 3). At the time, this recommendation represented a sharp departure from Medicare's historic policy of not reimbursing drugs used on an outpatient basis. Subsequently, the Catastrophic Health Insurance Act of 1987 authorized Medicare reimbursement of outpatient drugs on a widespread basis.

The final report of the task force (Task Force 1986), published in April 1986, made recommendations that were numerous and sweeping in scope and nature. For example, to facilitate organ donation the following steps were recommended: that all health professionals "voluntarily" accept responsibility for identifying prospective donors and notifying organ procurement agencies; that hospitals adopt "routine inquiry/required request" protocols; that the Joint Commission on Accreditation of Hospitals adopt a standard for all acute care hospitals that required affiliation with an organ procurement agency as well as policies and procedures for identifying donor prospects and giving donation opportunity to next of kin; that the Defense Department and Veterans Administration require their hospitals to adopt required request protocols; that HCFA establish as a condition of participation that certified hospitals adopt required request policies; that all states enact required request legislation; and that model legislation for the states be developed by the Commission for Uniform State Laws. Although the task force urged action by health professionals and hospitals on a voluntary basis, by a national private standard-setting body, and by state legislatures, it clearly regarded such action in instrumental terms, not as an alternative to federal government action. The task force emphasized its residual reliance on, and preference for, the regulatory authority of the pertinent federal agencies.

Regarding organ procurement, the task force recommended that both organ procurement agencies and procurement specialists be certified. In addition, reacting

20. Pub. L. No. 98-507.

to what it viewed as unseemly competition among such agencies, it recommended that only a single procurement agency be certified in "any standard metropolitan statistical area or existing organ donor referral area, whichever is larger" (ibid.: 5, 59). It did so with virtually no analytical support for this recommendation, merely citing several witnesses who testified before it. Administrative centralization, in its view, was more efficient than decentralized competition.

Organ sharing, and thus access to organ transplantation, was to be promoted through "a single national system." Rules of organ distribution based on immunologic status and blood type were recommended. The ability to pay for a transplant was ruled out as a basis for determining access; public and private health insurance for heart and liver transplantation was urged, and a program of public funds was recommended for medically eligible individuals who lacked money. Equitable access was to be based "solely on objective medical criteria that are applied fairly and are open to public examination" (ibid.: 8). The commercial sale of organs was condemned. It was recommended that no more than 10 percent of all cadaveric transplants in any center be performed on nonimmigrant aliens, and that the latter receive consideration only as a last resort.

The task force broke new ground in recommending "that each donated organ be considered a national resource to be used for the public good" (ibid.: 9). The precise meaning of this concept was not fully developed. The designation of "donated" organs as a national resource, however, appears to carry the policy discussion to the threshold of federal government ownership of body parts and a presumed consent organ donation regimen.

The task force also recommended that the number of transplant centers be limited by means of "an explicit, formal process using well-defined, published criteria" (ibid.: 12). Kidney, heart, and liver transplant centers should be designated by DHHS on the basis of minimum criteria for "facility requirements, staff experience, training requirements, volume of transplants to be performed each year, and minimum patient and graft survival rates'" (ibid.: 12).

The task force disputed whether there existed a relationship between the volume of transplant procedures performed and the outcomes realized, as measured by patient survival. A majority of the task force members, reflecting the views of the large transplant centers, held that such a relationship did exist and recommended that no centers performing fewer than 50 procedures a year be certified. A minority, using the same data on which the majority had rested its case, filed a dissent that demonstrated no difference in outcomes between centers performing 50 or more procedures and those performing 30–49 procedures. Remarkably, these different interpretations of the same data were resolved by voting.

Following the recommendations of the task force, Congress extended the statutory underpinnings of federal policy on organ transplantation in 1986[21] by establishing the requirement that a hospital have a written protocol for making routine inquiries of potential organ donors as a condition of participation in Medicare. Congress also required that hospitals conducting organ transplants be members

of the Organ Procurement and Transplantation Network in order to participate in Medicare or Medicaid. It further required that in order for organ procurement organizations to be reimbursed for procurement costs, they must comply with the provisions of the 1984 legislation and be members of the OPTN. The 1986 legislation also provided for the reimbursement of immunosuppressive drugs administered to transplant patients on an outpatient basis.

Given developments foretold in the 1984 legislation and under discussion by the task force, the Southeast Organ Procurement Foundation (SEOPF) sought to expand from a regional to a national entity by establishing the United Network for Organ Sharing (UNOS). In so doing, SEOPF provided the administrative framework and computer network that became the basis of UNOS.

Major political issues of organ transplantation

Several political issues raised by the above overview deserve extended discussion. They do not exhaust all possibilities; a different set might have been chosen. But the issues considered below attempt to go beyond the working assumptions of current policy participants and analysts to address several broader concerns.

The role of the media. The mass media inform the public, explain complex issues in relatively simple terms with varying degrees of impartiality and balance, and dramatize the dilemmas of political choice. A growing literature addresses the effects of television on political campaigns, especially the race for the presidency. The role of television in the development of particular public policies, however, has yet to be examined systematically. Clearly, the subject deserves serious research.

Although we have no analytical basis for knowing how the media have influenced transplantation policy, it appears intuitively and anecdotally that newspapers, television, and occasionally radio have exercised and continue to exercise a powerful influence. Fox and Swazey (1974) noted this some time ago.

Newspaper coverage of organ transplantation has been extensive in the past decade. An analysis of the *New York Times Index* entry for "transplants" for the years 1982 through 1986 shows increasing coverage in column inches of index, number of directly cited stories, and number of "see also" stories, as indicated in Table 1.

Television coverage of transplantation has also been extensive. Television provides a platform for advocacy for parents seeking help for their child, for physicians cast as caring experts, and for government officials. Charles Fiske, father of Jamie, systematically developed a public relations campaign to obtain the donation of a liver for his young daughter. The long-lasting effect of the Fiske campaign was

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21. Pub. L. No. 99-509.

Table 1. New York Times Index for "Transplants": 1982–1986

	1982	1983	1984	1985	1986
Index column inches	2	5 ¾	5 ⅜	6 ⅞	12 ¼
Index transplant stories	5	11	10	11	22
"See also" references					
Heart	1	6	50	51	48
Liver	9	10	8	1	5
Kidney	2	7	1	1	8
Other[a]	7	8	10	4	5
Total transplant stories	24	42	79	68	88

a. Includes eyes and eyesight, lungs, bones, brains, and Parkinson's disease.

highlighted in November 1987 when stories appeared about the fifth anniversary of Jamie's transplant.[22]

At the Conference on Families (for families of organ donors, transplant recipients, and patients awaiting a transplant) on 4 December 1985, participants heard DHHS secretary Margaret Heckler describe an assignment from President Reagan to make a special appeal for a liver for Ryan Osterbloom, which she did on television. Ryan's mother, Karen Osterbloom, followed Heckler's appeal and discussed the effectiveness of media attention and publicity. Ryan received a liver two days after the appeal, as did one other child, and many organ donor cards were signed in response (DHHS 1985).

Ted Koppel's "Nightline" program of 14 April 1983 was cited above. In addition to that twenty-minute segment, Koppel dealt with organ transplantation on nine other occasions from 1982 through July 1988.[23] The ABC News program "20/20" ran five segments on transplantation from 1982 through 1986.[24] And "The MacNeil-Lehrer News Hour" devoted thirteen major segments of its one-hour program to organ transplantation from 1983 through mid-1988.[25]

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22. Appropriately, on 27 June 1988, the first day of the Vanderbilt University symposium at which the papers in this volume were presented, *USA Today* carried a front-page picture of the Fiske family inaugurating the Family Inn, a residence for families with relatives in nearby hospitals.

23. The subjects and dates of these segments were: "Organ Transplants," 18 November 1982; "Organs for Sale," 5 October 1983; "Organ Transplants and the Media," 26 September 1984; "Heart Patients in Limbo," 13 December 1984; "Medical Ethics—The Tucson Transplant," 8 March 1985; "The Future of Heart Technology," 21 October 1985; "The Fate of the Mechanical Heart," 6 August 1986; "Infant Transplants and Medical Ethics," 16 December 1987; and "Fetal Transplants," 6 January 1988.

24. The subjects and dates were: "A Gift of Life," 21 October 1982; "The Rejection Factor," 15 November 1984; "A Second Chance at Life" and "The Highest Bidder," 24 April 1986; and "No Money for Their Lives," 5 June 1986.

25. The subjects and dates of these segments were: "Cyclosporine," 8 September 1983; "Organ Donor Controversy," 22 September 1983; "Questions Raised: Baby Fae," 30 October 1984; "The Baby Fae Case," 16 November 1984; "Life after Transplant," 28 February 1985; "The Tucson Transplant: Was It Ethical?" 7 March 1985; "Marrow Transplants," 15 May 1985; "Transplant Troubles?" 21 October 1985; "Transplants," 15 July 1986; "Transplant Ethics," 27 November 1987; "Transplants," 17

What are the extent and influence of newspaper and television coverage of transplantation? Although good measures are lacking, we can draw the following conclusions. First, the plight of the identified life of the potential transplant recipient is and will be widely publicized. Second, organized public relations campaigns on behalf of such individuals have practically become the norm. Consequently, we must consider the effect on the body politic of such campaigns, including the prospect that we will become inured to such spectacles. Third, to the extent that we value deliberation, the acquisition of data, and the rational weighing of alternatives (including consideration of costs), we must acknowledge that the mass media complicate public decisionmaking. Finally, to the extent that public policy decisions involve choices between allocating scarce resources to expensive, highly publicized procedures for a few identified lives and using those resources to finance basic health care for a larger number, the press and television will skew decisions in the direction of the few.

The orientation toward organ procurement. The organized acquisition and sharing of organs for kidney transplantation began in 1969 when the PHS organ procurement contractors at the Medical College of Virginia and the University of Virginia initiated the efforts that led to the creation of SEOPF. In the mid-1970s, the Centers for Disease Control launched a venture in applied epidemiology, seeking to identify the hospitals in which deaths were most likely to generate usable kidneys and to analyze how organ procurement teams could increase their access to such potential donors.

In the past five years, however, the analytical effort has shifted toward organizational modifications in the procurement system—away from the individual procurement agency and toward the federal government. This more recent administrative emphasis has resulted in several policy actions. First, the federal government has acknowledged the distinction between independent and hospital-based organ procurement organizations (OPOs) and has adopted policies that favor the independent agencies (Prottas 1985, 1989; Task Force 1986). It has done so on the basis of data that have never been published; thus independent validation of its analysis is precluded. Second, the federal government has stipulated that there be only a single OPO for each standard metropolitan statistical area, on the assumption that competition among OPOs results in fewer organs. This policy is directed at several large cities (like New York, Chicago, and Los Angeles) that have multiple transplant centers and have had multiple OPOs. The policy rests on practically no analysis, by either the task force or anyone else. No detailed case studies of the key cities appear in the literature, even though the single OPO policy is hardly without controversy. Third, a particular governance structure for inde-

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December 1987; "Transplant Coverage," 3 March 1988; and "Transplantation—Who Shall Pay?" 8 April 1988.

Table 2. Transplant Procedures: 1983–1987

Procedures	1983	1984	1985	1986	1987
Liver	164	308	602	924	1,159
Heart: DHHS	172	346	719	1,368	1,441
Heart: International Registry	161	341	680	1,141	1,441
Kidney	6,112	6,968	7,695	8,976	8,967

Sources: Liver: DHHS Health Services Resources Administration, Division of Organ Transplantation; heart: DHHS Division of Organ Transplantation, University of Minnesota, International Heart Transplant Registry, personal communication from Michael Kay; kidney: 1983–86, HCFA; 1987, preliminary data from HCFA, personal communication from Paul Eggers.

pendent organ procurement organizations (IOPAs) was recommended by the task force and incorporated into federal guidelines as a condition for receiving a supporting federal grant. Fourth, the national Organ Procurement and Transplantation Network was implemented by a contract between the Health Resources and Services Administration (HRSA) and UNOS (McDonald 1988). There is currently a debate about whether a federal agency that is administering a federal statute can delegate public authority by contract to a private, nonprofit organization. Fifth, OPOs, which are also private, nonprofit entities, have been required to join the OPTN network in order to be reimbursed by Medicare for organ donation costs. Sixth, all hospitals participating in Medicare are now required to establish a written policy of required request to ensure that all prospective donors (i.e., individuals known by the hospital to be dying) or their next of kin are asked about their willingness to donate organs for transplantation. Seventh, complex rules governing the distribution of organs have been recommended by the task force, incorporated by HRSA in the contract provisions with UNOS, and adopted by UNOS in a somewhat modified form. These rules stipulate when organs should be shared between transplant centers as a function of matching between donor and prospective recipient, and limit the export of organs outside the country and the transplanting of U.S. kidneys into nonimmigrant aliens.

In short, the federal government has introduced a number of organizational changes in the organ procurement system in order to increase the number of organs available for transplantation and to ensure their equitable distribution. There are enough legal, ethical, and political issues in these developments to warrant several papers on the politics of transplantation. Here I will focus not on a detailed analysis of these developments but on the issue of how this new organ donation, procurement, and distribution system has performed.

The first year in which many of these policy changes were fully deployed was 1987—all save required request, which became effective in November 1987. It is not too early to ask what the data suggest. The number of liver, heart, and kidney transplant procedures performed are shown in Table 2. These data indicate that

the number of liver transplants increased by 5.6 times from 1983 through 1986, growing by roughly 300 procedures in 1985 and 1986 and by 235 (or 25 percent) from 1986 to 1987. The data for heart transplants show nearly an eightfold increase from 1983 through 1986, following by an absolute increase of 73 procedures (or 5 percent) from 1986 to 1987. The International Heart Transplant Registry data, in contrast, show a sevenfold increase from 1983 through 1986 and an absolute increase of 300 (or 26 percent) from 1986 to 1987 (International Society for Heart Transplantation 1988). Kidney transplants grew by 2,864 (or 49 percent) from 1983 through 1986. Data from HCFA for 1987, however, show a slight absolute decrease from the previous year, the first time this has occurred since 1978.

Clearly, caution must be exercised in interpreting these data. The liver transplant data may reflect a momentary slowing in an otherwise rapid rate of growth, or they may mark a permanent inflection in the growth curve. The data for heart transplants reflect, at minimum, a serious need for consistency among the data collection agencies. UNOS, for example, published the HRSA data cited in the table in its 1987 report (UNOS 1987). On the other hand, the International Heart Transplant Registry is the subcontractor to UNOS for heart transplant data. If the government data are valid, 1987 saw a marked decrease in the rate of heart transplants performed, and thus in the rate of acquisition of donor hearts; if the registry data are valid, however, they indicate a continued strong upward rate of growth.

The kidney transplant data provided by HCFA show that fewer kidney procedures were performed in 1987 than in 1986.[26] These data are disturbing, even if they reflect only a momentary slowing of growth, partly because this procedure substitutes a more effective, less costly treatment than dialysis for patients with end-stage renal disease. They are also disturbing because the number of kidney transplants has been increasing at an annual rate of 12–15 percent for some time, and a sudden flattening of the curve is far more startling and ominous than a gently sloping inflection.

Let me suggest that the organizational changes in the transplantation procurement system have been driven by a need orientation, not a performance orientation. Need, in this case, is defined as the difference between the actual number of transplant recipients and the potential number who could benefit if donor organs were not scarce. The need orientation looks at the gap between actual and potential transplant recipients and then focuses on closing the gap, which leads to activity that takes on the semblance of a moral crusade.

A performance orientation, in contrast, focuses on the annual rate of growth in actual procedures performed and regards an annual increase of 10 percent as more than acceptable, even exemplary. It assumes that the gap between actual and po-

26. Although UNOS has not published actual 1987 data, its published estimate for kidney transplants exceeds that of HCFA. Here again we see the need for consistency among the several agencies responsible for transplant data.

tential beneficiaries will not be closed because increased success will generate increased demand for transplants. The policy objective that flows from this orientation, however, is not a moral crusade but an effort to maintain the rate of growth. It is clear, for example, that such a rate of increase in kidney transplants has begun to have important quality and cost effects on Medicare's ESRD program (Eggers 1988).

The need orientation has undergirded the government's recent efforts to reorganize the organ procurement system. In the process of reorganization, a centrally designed system is being imposed on a heretofore decentralized system in the interests of increasing the number of organs obtained. Implicitly and explicitly, the grassroots, decentralized system has been judged inadequate. Why, then, should we witness even a momentary setback in numbers of kidney transplant procedures and numbers of donated organs obtained?

Let me suggest an interpretation, less as a conclusion than as a hypothesis against which data in successive years should be tested. It is possible that the system may have been overorganized. Perhaps the scarce time and energies of OPO professionals are being diverted from the acquisition of organs to matters of administration, organization, reorganization, and attendant turf battles, leading to nontrivial disruptive effects.

A second possibility has also been advanced. The request for organ donation is a complex encounter involving procurement professionals, the attending physician and hospital personnel who have been caring for the recently deceased potential donor, and the family of the deceased. The requirement that hospitals now have written protocols for asking about organ donation of all potential donors may have altered the character of that encounter. The request for organ donation that was sensitive to the family, the stage of their grief cycle, and to the attending health professionals may now have become a bureaucratic requirement to be fulfilled. No reason exists to think that major changes in social relations can proceed without experiencing the equivalent of social friction.

The procurement system actually had been performing rather well, as judged by the number of new organs that were being acquired each year. Did it need the adjustments it received? The 1987 data suggest some difficulties; the data for 1988 will tell whether this stage is transitory.[27]

Facility certification. The certification of facilities raises another set of questions. As discussed above, the government chose to restrict the number of centers that could be reimbursed for kidney transplantation by requiring conditions of participation for such centers (including volume of procedures per year) in addition to those required of the host hospital for participation in Medicare.

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27. In January 1989, anecdotal reports from various parts of the country strongly suggest that 1988 will be no better than 1987 in terms of the number of kidney transplants performed, and that the 1988 numbers may actually be worse. HCFA data will not be available until mid-1989.

The task force, seeking to limit the diffusion of transplant centers, recommended that approved transplant centers be designated on the basis of experience, logistic medical support, volume, and graft and patient survival rates. The task force considered a minimum annual volume of 12, 15, and 25 procedures, respectively, to be appropriate for heart, liver, and kidney transplant centers. The kidney transplant recommendation exceeded the requirement of 15 procedures a year established by Medicare regulations in 1976.

Recently published HCFA regulations for heart transplantation require centers to have performed 12 procedures in each of the past two years and another 12 in the period before that in order to apply for participation in the Medicare program.[28] The presumption is that evidence of an institutional commitment to heart transplantation is a justifiable way to limit entry. Performance standards, as measured by the center's patient survival rates as compared to the experience of leading centers, are also required of new entrants.

This policy imitates other public and private bodies that have sought to limit reimbursement for transplantation to designated centers, based either on a minimum volume requirement or on an outcomes requirement. Illinois, for example, stipulated in 1986 that transplant centers wishing to participate in the Illinois Experimental Organ Transplant Program for heart, liver, heart/lung, and pancreas transplantation must have performed six procedures before application. Blue Shield of California will reimburse a transplant center for heart transplantation as long as it meets the performance outcomes of Stanford as measured by one- and two-year patient survival.

Sloan et al. (1989) review the literature regarding the relationship between volume of procedures and outcomes for kidney transplantation, finding no evidence for a straightforward volume/outcome relationship or for economies of scale among larger-volume centers. Although they find a rationale for regionalizing kidney transplant centers on the basis of quality and cost through some process of designating specific centers for reimbursement purposes, they find little evidence to support such policies and regard the risks of establishing irrevocable franchises as unattractive.

The weight of analysis regarding limiting the number of transplant centers for quality and cost reasons increasingly casts doubt on the utility of establishing permanent franchises. Facility certification, however, may be useful as a policy tool for limiting the number of centers reimbursed for *new* surgical procedures until they can be properly evaluated for purposes of setting performance standards, in terms of patient outcomes, that other centers might be expected to meet (Rettig 1987). This suggestion leads to the issue of evaluating new surgical procedures, however, to which we now turn.

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28. 52 Fed. Reg. 10,935 (1987).

Evaluation of surgical procedures. In the past decade, a body of literature has developed that indicates that few medical and surgical procedures and technologies are evaluated with any rigor and that the evidence for their efficacy and effectiveness is frequently quite low in quality (Eddy 1988). The case has been made that a more systematic evaluative process is needed for medical and surgical procedures and technologies (Bunker, Hinkley and McDermott 1978; Institute of Medicine 1985).

HCFA has begun to emphasize its mission of quality assessment and assurance in addition to financing care. The peer review organizations (PROs) represent one step in this effort. Another step is the annual publication of hospital mortality data for the purpose of improving the information about quality of care that is available to providers and beneficiaries. Most important, a broad program of research and analysis directed toward establishing the effectiveness of Medicare-financed care has been launched (Roper and Hackbarth 1988; Roper, Winkenwerder, Hackbarth, and Krakauer 1988).

Wennberg (1988) has noted the emergence of the evaluative clinical sciences and the importance of systematically assessing the outcomes of medical and surgical procedures. He and his colleagues have analyzed the variations in small geographic areas of the utilization and outcomes of various procedures, including the benefits, risks, and costs of prostatectomy (Barry et al. 1988; Fowler et al. 1988; Wennberg et al. 1988). Wennberg has pointedly noted the absence of institutional mechanisms for evaluating surgical procedures and has contrasted this to the extensive evaluation of new drugs.

Brook and colleagues have examined the appropriateness of various procedures, including coronary artery bypass surgery and carotid endarterectomy. They have established indications for the appropriate use of a procedure based on a systematic literature review, a consensus exercise by a panel of experts, and the evaluation of actual medical chart data for clearly appropriate, not clearly appropriate, and clearly inappropriate use (Chassin et al. 1987; Winslow et al. 1988).

New medical and surgical procedures are introduced into practice with little, if any, systematic review (Bunker et al. 1978). The Food and Drug Administration (FDA) reviews and approves all new drug and many new medical device applications for safety and efficacy on the basis of data obtained in randomized controlled clinical trials. Typically, public and private third-party payers await FDA approval before considering drugs and devices for coverage and reimbursement purposes. No such regulatory mechanism screens new medical and surgical procedures before their introduction.[29]

Bunker et al. (1977) laid out an extended argument for evaluating surgical procedures, devoting a section of their volume to surgical innovation. Subsequently,

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29. The weak exception is found in the institutional board review for the protection of human subjects and informed consent.

Bunker et al. (1978) analyzed the introduction of four new surgical procedures: shunt surgery for portal hypertension, coronary artery bypass graft, jejunocolic and jejunoileal bypass, and total hip replacement. The first two procedures are intended to relieve conditions that threaten life, the third and fourth to relieve conditions that impair the quality of life. With the single exception of total hip replacement, which got caught in the FDA drug approval process because a question was raised about the safety of methylmethacrylate, the other procedures were introduced without controlled clinical trials or carefully designed observational studies.

The logic behind this pattern of introduction without evaluation was, "If the condition to be treated presents an immediate threat to life, if the proposed treatment appears to be physiologically sound, if the treatment appears to be dramatically successful, and if no reasonable therapeutic alternative is available, its efficacy is apt to be considered self-evident" (Bunker et al. 1978: 938). This logic describes the justification used in 1983 for liver transplantation.

The pervasiveness of the above logic notwithstanding, Bunker and his colleagues called for a strategy of evaluation that includes the following stages: feasibility studies, in which the physician-investigator "develops and refines the new procedure and then defines diagnostic criteria for its evaluation" (ibid.: 940); collaborative clinical trials (randomized or observational), in which "documented protocols are followed and in which all relevant quantitative evidence is collected and analyzed according to predetermined statistical criteria"; and then, after efficacy has been established, release for more general use.

A dramatic recent example of surgical experimentation in the absence of justifying data is provided by neural transplantation. Surgeons in Mexico City transplanted adrenal tissue into the brain of humans as a means of treating Parkinson's disease. Initial reports were so stunning that American surgeons followed apace. Now, however, one year later, the results of procedures performed in this country have failed to confirm the Mexico City results. Moreover, the latter are being scrutinized very carefully and do not presently appear to be holding up. Voices of reason are calling for a more orderly, data-oriented approach to determining the merit of this new procedure (Sladek and Shoulson 1988; Kolata 1988; Rohter 1988).

Less starkly, but no less insistently, organ transplantation raises a set of questions similar to those surrounding neural transplantation and other surgical procedures. Kidney transplantation was judged effective by a special task force twenty years ago in the context of a similar judgment then being made about hemodialysis; the former, when successful, was preferred to the latter by almost all observers (Committee on Chronic Kidney Disease 1967). Controversy between transplant surgeons and nephrologists regarding the preferred treatment given the most likely outcomes seesawed back and forth until the advent of cyclosporine in the 1980s.

Heart transplantation was evaluated by a special study called for by the secretary of DHHS. This study by Evans et al. (1984) followed more than a decade of careful research by Shumway at Stanford. During the study, cyclosporine was introduced and permanently altered the context within which the results were reported. The

study emerged with the Stanford performance as the "gold standard" for the heart transplant community.[30]

The liver transplantation evaluative experience, however, stands in marked contrast to these other two procedures. Unlike kidney transplantation, no artificial liver machine existed for comparison purposes. Unlike heart transplantation, no lengthy study like the National Heart Transplant Study was conducted. The evaluation raises some troubling questions about the assessment of liver transplantation during the period from 1982 to 1984 and about the legacy of decisions made then.

The "evaluation" focused on the 1983 NIH consensus development conference on liver transplantation. The stratagem involved, as we have indicated, a two-step process of obtaining a consensus statement that allowed advocates to claim that the procedure was no longer experimental and, on the basis of that statement, securing a HCFA coverage decision that became binding for other third-party payers.

The NIH consensus development process has recently been critically reviewed by several observers. A paper from Canada reported on a consensus effort designed to differentiate itself from the NIH process by placing greater emphasis on the role of evidence derived from the clinical literature. "The results of this study," it concluded, "indicate that a public consensus process that is structured to emphasize the important role of evidence does lead to a panel consensus that reflects this orientation" (Lomas et al. 1988: 3004). In a discreet editorial, the former acting director of the NIH Office of Medical Applications of Research observed: "More strict reliance on evidence in consensus development might have been promoted if staff preparation for U.S. conferences routinely included a data synthesis for the panel" (Jacoby 1988). Based on his observations of 30 conferences held from April 1984 through July 1987, Jacoby was led "to place greater value on techniques of data synthesis and to reemphasize commitment to basing consensus strictly on examination of evidence by a neutral panel." Wortman et al. (1988) compared their evaluation of eight consensus conferences held between 1980 and 1982 with more recent evidence and found that "the major problem uncovered—selection bias, particularly with respect to the choice of questions and panelists—still remains a significant threat to the credibility of the consensus process."

In truth, the NIH process of consensus development was not designed to review procedures for effectiveness judgments related to third-party payer coverage decisionmaking. Given the general criticisms noted above and the fact that NIH eschews economic considerations in the consensus development process, its political use for this purpose in the instance of liver transplantation represents an abuse of an otherwise useful process.

Congress did not seek rigorous data on the effectiveness of liver transplants in 1983 and 1984. Rather, it highlighted the individual lives involved, accepted at

30. In three interesting papers, Buxton (1987, 1988) and his colleagues (O'Brien 1987) analyzed the evaluation of heart transplantation in the United Kingdom.

face value the testimony of Dr. Starzl about effectiveness, and pressed for a favorable consensus conference statement. The 1984 legislation, as a result, did not charge the task force to review the effectiveness of liver transplants, even though a case could be made for doing so. Nor did the task force review any data for the efficacy or effectiveness of liver or any transplant procedure. Ironically, in retrospect, a leitmotif that ran through the 1983 Gore hearings was the need for more technology assessment of medical procedures.

The absence of an adequate institutional mechanism for evaluating new surgical procedures has created a residual set of concerns about liver transplants. Good data are still scarce and not readily available to the interested public. HCFA collects data on kidney transplantation, and worldwide data on heart transplantation have been gathered since 1981 on a voluntary basis by the International Heart Transplant Registry, but only late in 1987 did the NIH contract with the University of Pittsburgh to develop a registry for liver transplantation, and then only for six centers.

Concern about the absence of data is only a proxy for anxiety about the outcomes of liver transplantation. Advocates praise the procedure highly (Gordon et al. 1987; Williams et al. 1987; Colonna et al. 1988). However, critical voices are also being raised (Koff 1987; Riely 1987; de Groen et al. 1987). Data on quality of life, measured in a way similar to the measures used by the National Heart Transplant Study, are not routinely reported. Spectacular failures continue to be reported in the press. Several states, as will be indicated below, have had very unsatisfactory experiences. Under circumstances of continuing questions about effectiveness, the extremely high cost of the procedure creates its own tension.

Of the three procedures—kidney, heart, and liver transplantation—heart transplants were evaluated in a way that corresponds most closely to Bunker et al.'s concern for careful observational studies in circumstances where randomized trials are ruled out on ethical grounds. Although it is not clear whether this evaluation represents an institutional model for assessing new surgical procedures, it is certainly a pattern that could be deployed to good effect relative to liver transplantation.

We also suggest one plausible institutional response to cases of new surgical procedures like liver transplantation. Where it has been demonstrated that a procedure is no longer experimental but still falls short of having met a rigorous review for effectiveness, it may be useful to implement an evaluative mechanism for this intermediate stage. Where a single facility, like Pittsburgh, has an arguable claim to having demonstrated the effectiveness of a procedure, it might be worthwhile to consider a system for provisional coverage of a selected number of centers for a three- to five-year period, reviewable annually. Specific clinical indications or patient selection criteria might be stipulated, a regional criterion might be used to ensure some measure of geographic access, and a data collection protocol might be required to assure the conduct of a well-designed observational study.

This paper does not permit the further exploration of the issues surrounding this suggestion of selective coverage. I have dealt with some of the advantages and

antages of such a proposal elsewhere (Rettig 1987). Given the absence of an institutional mechanism for assessing new surgical procedures, however, some careful attention should be given to the general proposition of a time-limited, selective coverage policy.

Financing, distributive justice, and rationing. The crux of the policy discussion of transplantation involves the intertwined issues of financing, distributive justice, and the rationing of medical care. Financing organ transplantation, the key issue, has been kept off the federal government policy agenda. Basically, the Reagan administration did not wish to discuss it. Congress acceded to this wish largely because of the pressure of the deficit and national debt on all federal spending. Moreover, the Medicare program represents a very imperfect mechanism for financing health care for children or adults in the prime of life.

Another factor keeping financing off the table has been the dominance of what might be called "the ESRD metaphor." The administration and Congress have tended to see transplantation as a fiscal blockbuster due to high unit costs and very high estimates of need. It might have been viewed as an insurable risk: minimal incentives exist to encourage overuse, and the scarcity of organs restricts the number of procedures to a few thousand each year for both hearts and livers, thus limiting aggregate costs. For example, many Blue Cross and Blue Shield Association plans, as well as many commercial health insurance firms (at least those with many subscribers), have seen transplantation costs as absorbable.

One of the more fascinating aspects of the policy discussion of transplantation at the federal level has been the virtual absence of discussion about distributive justice. The task force restricted itself to the ethical issue of organ distribution. Whether resources ought to be spent for other purposes, including health purposes, was not addressed.

Access to basic care for the estimated 33 million or more Americans who are uninsured (Davis 1988: 3171) will certainly rank high on the national agenda for the 1990s. Basic needs in maternal and child health surely rank high on any list of national needs. The unmet needs of the elderly for long-term care also deserve high priority. In light of these well-documented deficiencies in the U.S. health care system, an increasing number of commentators are drawing attention to the trade-offs involved between basic care for the many and expensive, even though lifesaving, care for the few.

It has been left to the states to take tentative first steps in addressing this fundamental political issue. In Virginia, the Board of Medical Assistance Services, which determines policy for the state Medicaid program, recently voted unanimously to terminate funding for liver transplants but to continue funding for kidney and corneal transplants, pending public hearings in the fall of 1988 and the subsequent issuance of a final rule.[31] Children previously eligible for transplant be-

31. The author thanks Ruth S. Hanft, a member of the board, for discussing this case with him.

nefits can continue to receive them until a final rule is published. This eleven-member board includes six nonprovider and five provider representatives (a doctor, a dentist, a hospital administrator, a nursing home administrator, and a pharmacist). The background is as follows.

Virginia governor Gerald Baliles, alarmed by the projected incremental costs of $145 million for the Medicaid "current services program" (no change in level of services) for the 1989 fiscal year, tried unsuccessfully to impose a "head tax" on hospitals and nursing homes. Rebuffed by the Virginia General Assembly, he established a commission on costs and indigent care, but no report is expected until after the 1989 session of the General Assembly. The prognosis for a "lasting solution to a funding crisis in Virginia's Medicaid program" is gloomy (Melton 1988).

In this context, the Board of Medical Assistance Services recommended that the 1988 session of the General Assembly extend maternal and child health services up to 100 percent of the poverty level and up to age 5, adopt case management procedures for costly cases, and increase the fees of primary care physicians. The legislature agreed to 100 percent of the poverty level up to age 1, barely agreed to case management, and provided only a small increase in fees for primary care physicians.

Regarding liver transplantation, the board had earlier agreed to pay for transplants for children 18 or younger with biliary atresia. A state court advised the board that age was a questionable criterion in the event of a court challenge, and that the procedure could probably not be limited to a single diagnosis. The board reviewed the data on the six individuals who had received liver transplants—two each at the University of Pittsburgh, Johns Hopkins University, and the Medical College of Virginia. Five had died within a year of the operation at a relatively high cost to the Medicaid program. Facing a probable bar to discriminating on grounds of age or diagnosis, the board opted to terminate financing for liver transplantation entirely pending public hearings and a final rule. In fact, the board expects this matter to be settled by either the General Assembly or the courts.

In Oregon, the state legislature in 1987 adopted a budget for the state Medicaid program that eliminated payment for all transplantation procedures save kidney and cornea (Welch and Larson 1988; Egan 1988). In doing so, it accepted a recommendation to the Division of Adult and Family Services that the resources be allocated instead to services for some 2,000 indigent pregnant women without prenatal care. Since the policy was adopted, Coby Howard, a young child needing a bone marrow transplant, has died because funds could not be raised to pay for the procedure. The mother of another child needing the same procedure has moved to neighboring Washington state, which finances the procedure for Medicaid patients without requiring a minimum residency period.

Although the legislature acted with little public discussion in 1987, it did so with a relatively clear understanding of its action. The State Emergency Board, composed of nine legislators empowered to supplement the biennial budget be-

tween sessions, declined to increase the state health budget. More important, the president of the Oregon Senate, John Kitzhaber, M.D. (1988: 22), has placed the decision in the following context:

> It is important to understand this decision and the underlying policy which it reflects. This was only superficially a transplant issue. Rather, it was an economic issue, one which, in Oregon and elsewhere, perhaps can be postponed but not avoided. The question is, can Oregon (or any other state) afford to pay for all the health care now available for anyone who might benefit from it? The transplant issue was a catalyst for a much more far-reaching policy debate, one which has forced us to confront our fiscal limits, our lack of a meaningful health care policy, and the eventual inevitability of explicit health care rationing.
>
> State legislators in particular should understand limits. We are acutely aware that there is a limit to the level of taxation the public will tolerate. Given that fact, and recognizing that deficit spending is constitutionally prohibited in most states, there remains a finite budget from which to fund the activities of state government. When money is spent on one set of services, it is, by definition, not available to spend on other services. Health care for the poor is unquestionably a governmental responsibility. States also need to pay for law enforcement, infrastructure, public schools, higher education, and for an enormous variety of other essential social programs. Health care services must compete with all the other legitimate services state government must provide.

It is important to note that an important Oregon grassroots effort aimed at establishing public understanding of the allocation dilemmas in health took place in the period before the legislature acted. A 1982 conference held to develop public awareness and consensus on bioethical issues regarding allocation addressed two basic questions: "(1) How does society value expensive curative medical care relative to preventive services being progressively curtailed in government budgets? (2) Can the present implicit rationing of health care be made explicit and congruent with community values?" (Crawshaw et al. 1985: 3213).

Following the conference, a volunteer effort coordinated by the three health planning agencies in the state in late 1983 organized a series of town meetings across the state. Some 300 meetings were held, involving more than 5,000 citizens. In the summer of 1984, a preliminary report was prepared for a statewide parliament held that October. The parliament produced a document entitled "Society Must Decide: Oregon Health Decisions Final Report." The report contained this conclusion:

> The process of discussion and debate led to a statement of principles that express basic values common to the participants. These principles recognize that good health is a kind of social benefit that, like happiness, cannot be

> guaranteed by the state. But the state can and should guarantee its citizens the right to pursue good health. While the pursuit of health is a matter of personal choice and responsibility, society through government should protect individual liberty to pursue good health. Since some causes of ill health are beyond the control of the individual, there is a societal responsibility to eliminate such causes whenever reasonably possible, whether they originate in nature or in social institutions. Collective financing of health care should be accompanied by community responsibility for the ethics of allocation and rationing policies (ibid.: 3215).

A detailed account of the 1987 and 1988 actions by the Oregon legislature (Welch and Larson 1988) made no reference to Oregon Health Decisions. Several papers explicitly link the legislature's decisions to Oregon Health Decisions (Crawshaw et al. 1988; Crawshaw 1988). Oregon Health Decisions, however, bears close attention. With the support of the Prudential Foundation, the Robert Wood Johnson Foundation, and the Hastings Center, it has been exported to other states around the country (Otten 1988). It represents a distinctly grassroots, Jeffersonian democracy or New England town meeting approach to the vexing allocational choices that society confronts when dealing with decisions to limit financing for transplantation (Capron 1988; Cole 1988).

Controversy over organ transplantation is but another instance of the growing tension between the allocation of resources to expensive procedures that may dramatically save a few lives versus directing those same resources to basic care for the many. The issue of distributive justice insistently claims our attention in broader terms than does the search for an ethical rule for distributing organs.

Distributive justice is better understood by the British. For all the limitations that might be found in the National Health Service, the British have embraced equity as a basic organizing principle, have accepted the reality that not all that can be done technically can be done financially, and have embedded their basic values—those affirmed and those foregone—in institutions that routinely make binding choices that affect the country's citizens.

Since the federal government has not addressed the financing of organ transplants beyond kidneys, the issue has been left to the states (and to private third-party payers). Rather than deplore this fact, we might consider the opportunity it confers through watchful waiting to learn about the fundamental issues, choices, and acceptable patterns of decision from state governments where scarcity is a binding constraint. Organ transplantation engages the states in a serious manner; the most fundamental characteristic of their response is reluctance to contribute their own resources for such procedures when they impose severe opportunity costs on the provision of basic services.

Conclusion

What general conclusions can we draw from the transplant experience? First, on one level, we witness again the impact of scientific and technical advance in

medicine. This advance not only extends clinical capabilities, but in the process raises an array of political, social, economic, and ethical issues. These issues, not the modest scale of the transplant enterprise, engage our attention.

Second, newspaper and television publicity about organ transplantation has been extensive and is likely to continue. Although we lack good analyses of media impact on transplantation policy, we can speculate with confidence that identified lives benefit even more from publicity than do the statistical lives of other legitimate, less visible claimants on scarce collective resources.

Third, the policy discussion, driven by a sense of unmet need, has at times taken on the character of a moral crusade. This is manifest most clearly in the efforts to reorganize the organ procurement system. The danger that now appears is that reorganization may impair the performance of the procurement system.

Fourth, a more rigorous means of evaluating new surgical procedures is suggested by the organ transplantation experience. This includes attention to the institutional mechanisms for assessing new surgical procedures. Selective coverage of a relatively few transplant centers may commend itself as such a means in that period when new procedures cease to be experimental but have yet to fully demonstrate their effectiveness. Better evaluation of effectiveness may also lessen the vulnerability of an expensive lifesaving procedure to becoming ensnared in the rationing controversy.

Fifth, the financing of transplantation is caught up in the complex and painful realization that we are running out of time and economic resources for paying for everything that it is medically possible to do. Aaron and Schwartz (1984), Evans (1983a, 1983b), Englehardt (1985), Englehardt and Rie (1986), and Callahan (1987) have contributed to this discussion, as have many others. The sense of limits is beginning to sink in. Distributive justice cannot be addressed easily by a body of experts. That issue may be best left to the political process; the Oregon and Virginia experiences reveal that elected officials and the public can come to grips with the central issues and arrive at binding decisions.

Calabresi and Bobbit's 1978 essay, *Tragic Choices*, remains one of the most important pieces written on the subject. Their argument, in brief, holds that there is no escape from painful allocative decisions for society, that society will attempt all manner of evasive maneuvers to escape the implications of that fact, that temporizing solutions will be sought that allay anxiety for a time, that such solutions will eventually break down, and that the cycle of "violence" will resume.

The last point is worth dwelling on for a moment. Americans, as a rule, are not accustomed to thinking that violence must be an essential ingredient of social life and social policy. The Oregon legislature's decision to restrict Medicaid payment for transplantation, followed by private fundraising campaigns focused on small, dying children, illustrates this point vividly. We may agree that Jeffersonian democracy or a New England town meeting approach to the issue of distributive justice has made headway. But who among us can, with equanimity, watch on television the spectacle of individual lives lost because of resources, not technical

capability, and not experience the tearing of the social fabric? Violence is the only term to characterize the situation.

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Liver Transplantation in Massachusetts: Public Policymaking as Morality Play

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Abstract. The experience of the Commonwealth of Massachusetts in handling the appearance of liver transplantation as a viable surgical procedure provides a useful case study of the utility of centralized decisionmaking on matters affecting the availability, use, and cost of a new and controversial technology. This article observes the early political pressures to provide Medicaid coverage for the procedure and the anomaly that, for a time, low-income persons had access to a procedure that the dominant Blue Cross plan was unwilling to underwrite and that a majority of employers was unwilling to pay for. An assessment of the performance of Massachusetts's regulatory institutions concludes that certificate of need and hospital rate regulation, while insulating providers from demand-side signals concerning the procedure, failed to provide alternative assurances that transplants would be done in, and only in, appropriate cases. The expert advisory committees used by the state in the decisionmaking process are found not to have been immune from the pressures that cause public officials to engage in posturing and symbolic action in confronting "tragic choices." Some final thoughts are offered on the alternative of leaving questions about the uses of technology to be faced in the private sector.

In 1982, Jamie Fiske, the infant daughter of Mr. and Mrs. Charles Fiske of Massachusetts, was dying of congenital liver disease. Her death was imminent, except for the possibility that a liver transplant—a difficult, risky and extremely costly surgical procedure considered by many authorities still to be experimental—could prolong her life, for months or years, under a lifetime regimen of drugs to prevent her body's natural rejection of the foreign tissue. No surgeons or hospitals

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in Massachusetts performed liver transplants at the time. Moreover, the Massachusetts Blue Cross and Blue Shield plans (MBCBS), the family's health insurers, advised the Fiskes that such an experimental procedure would not be covered under their policy.[1] Thus begins the complex morality play, *Liver Transplantation in Massachusetts*.

In addition to the Fiskes, the players in this drama include: two state-appointed commissions, composed of prominent citizen-experts; the state Department of Public Health; the state Medicaid program; MBCBS and Blue Shield's president, John Larkin Thompson; and, as a kind of Greek chorus, the omnipresent media. The role of "identified life"[2] is played by Jamie Fiske, whose plight precipitated a dramatic medical rescue and who has so far lived as happily ever after as her circumstances permit. Absent from the play, even as off-stage voices like the unborn children in *Die Frau ohne Schatten*,[3] are the "statistical lives" that policymakers reputedly find easier to ignore than identified lives in allocating public resources.[4]

The action takes place under the full glare of publicity. The setting, the Commonwealth of Massachusetts between 1982 and 1985, features a highly regulated health care system built on assumptions that were common in the 1960s and 1970s but that are not universally embraced in the United States today. To understand the plot of this drama, it is helpful to recognize that the political ethos of Massachusetts envisions a true health care "system" governed centrally in accordance with explicit public choices. Thus, although Jamie Fiske's fate was not directly in the hands of the commonwealth, the state government seemed to view itself as responsible for seeing that nothing so publicly heart-rending could happen again.

This review of the Massachusetts experience with liver transplantation treats it as a case study of how a centrally controlled health care system faces difficult choices concerning health care and health care technology. Despite its many special features, the problem of liver transplantation is not *sui generis*. Health care abounds with similar questions concerning marginal trade-offs between benefits and costs. Although few of them are as visible or as fraught with the characteristics of "tragic choices"[5] as organ transplantation, the basic dilemma of whether to

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1. Because the Fiskes had initially been guaranteed coverage for the transplant by an MBCBS employee, the Blues eventually agreed to pay for Jamie's treatment even though the procedure was technically excluded from plan coverage.

2. The special function of characters like Jamie—endangered individuals whose jeopardy could be relieved by heroic or extraordinary governmental action—in dramas of this kind has been observed by numerous critics. Interestingly, many, if not most, of these critics have been Harvard professors and citizens of Massachusetts (see, e.g., Fried 1969; Fuller 1949; Schelling 1968; Zeckhauser 1975; Evans 1983; Friedman 1984; see also text accompanying notes 24–26).

3. A well-known operatic fantasy by Richard Strauss and Hugo von Hofmannsthal.

4. See Havighurst, Blumstein and Bovbjerg (1976: 122, 140–45); see also references cited in note 2 and text accompanying notes 24–26.

5. The term is Guido Calabresi's (Calabresi and Bobbitt 1978). Tragic choices arise in situations where no decision can be satisfying because any choice necessarily sacrifices one or more irreconcilable

spend scarce resources to achieve a particular health benefit of possibly less than commensurate value is always the same. The choice of decisionmaking mechanisms, public or private, through which to address these inescapable trade-offs has been the fundamental problem of health policy in the United States (Havighurst and Blumstein 1975).

American society as a whole is somewhat less committed than Massachusetts to centralized decisionmaking on questions of what health services should be provided. Indeed, although the enactment of Medicare and Medicaid in 1965 started a seemingly inexorable movement toward such centralization of authority in government hands, recent years have seen a distinct movement in the opposite direction, particularly in federal policy (Meyer 1983; Havighurst 1986). Despite the promise of this new policy and some signs that hopes for it are being rewarded, it is still not clear that private choices can effectively ration expensive, potentially lifesaving therapies or that such rationing, if effective, would be acceptable politically. Many believe that effective and acceptable rationing can be achieved only by having government assume direct or indirect control of technology and health care spending. Although the Massachusetts experience with liver transplants provides no answers to these policy questions, it yields some insights into the relative merits of both approaches.[6]

Act one

Jamie Fiske's father successfully pleaded her need for a transplantable organ (and financial assistance) before the entire country, leading to a successful transplant at the University of Minnesota in November 1982. As a direct result of Jamie's case and the publicity it attracted, several things happened back home in Massachusetts. Several hospitals in Boston, all of them nationally prominent research and tertiary care centers, began expressing an interest in undertaking liver transplants. Other candidates for transplant surgery began appearing and pressing for financial support for the expensive lifesaving therapy. Such developments immediately focused attention and pressure on state government, because Massachusetts hospitals were not free to offer the service without a "determination of need" (DON) by state health planners[7] and because the state Medicaid program was one of the payers being asked to cover the cost. In addition, although MBCBS plans were private entities, they were finding it difficult both on medical grounds

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fundamental values. Scarcity is the fundamental condition that necessitates such choices. Not all choices are tragic, of course, and markets are usually tolerated to allocate mundane goods and services. Where the opportunity cost of a particular choice includes a highly visible possibility of a lost life or other personal tragedy, however, its potentially tragic character appears.

6. For other studies providing insight on technology assessment, rationing, and tragic choices in different health care settings, see Aaron and Schwartz (1984), Institute of Medicine (1985), Minnesota Coalition (1984), and Office of Technology Assessment (1982).

7. Mass. Gen. Laws Ann. ch. 111, § 25B (West 1977).

and as a public relations matter to insist that liver transplantation was still "experimental" and therefore not covered by their insurance contracts. MBCBS was hopeful that the state would take the heat either for denying the service or for authorizing it and the higher insurance premiums needed to pay for it. Under these circumstances, the commonwealth government did the predictable thing—it appointed a commission.[8]

The Fineberg task force and report. The Liver Transplantation Task Force (LTTF), which was created in December 1982, was charged by the commissioner of public health with the task of discussing several issues, including the question, "Should this type of program and procedures be encouraged or permitted?"[9] Notably, this charge directly raised the fundamental question of whether the state should allow livers to be transplanted at all. It envisioned a range of possible postures for the state, from prohibition to neutrality to active encouragement. Although outright suppression of either research on a new technology or use of a technology once developed would, in practice, raise serious political and legal questions, the LTTF was nevertheless asked to recommend what state policy ought to be.

The LTTF's report, known as the Fineberg report (Task Force 1983), was issued in May 1983. It described liver transplantation as

> . . . a technically feasible, extreme and expensive procedure, demonstrably capable of extending the lives of some patients near death, and with substantial uncertainties about optimal selection of patients, appropriate criteria for excluding other patients, optimal matching of donor organs and recipients, effectiveness under conditions of more widespread use, and the extent of benefits and costs (ibid.: 34).

The report recommended that liver transplants in Massachusetts be limited to one adult and one pediatric program with extensive data to be gathered from these programs in order to clarify the numerous "uncertainties" it had identified (ibid.: 36, 40–41).[10] The LTTF viewed both this data gathering and systematic evaluation of the procedure as vitally important.

In addition, the Fineberg report provided extensive cost estimates on liver transplantation, derived largely from data supplied by MBCBS (ibid.: 25). It identified

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8. This commission was the Liver Transplantation Task Force, which was created in December 1982.

9. Letter from Alfred L. Frechette, commissioner of public health, Commonwealth of Massachusetts, to Harvey Fineberg, Harvard School of Public Health, 27 December 1982, reprinted in Task Force (1983: B1–B2).

10. The report also recommended that liver transplantation be initiated under a special one-year DON exemption, so that the data gathered by the new programs could be evaluated before a final DON determination was made (Task Force 1983: 39–40). In a thoughtful discussion establishing the need for this data gathering, the report described liver transplantation as being somewhere "on the continuum between 'experimental' and 'established'" (ibid.: 5).

eleven cost components, ranging from preoperative expenses, surgery, and follow-up to the costs of complications, including rehospitalization and additional transplants (ibid.: 27). It concluded by estimating that the average cost per Massachusetts patient surviving one year after the transplant would be $238,800 (ibid.). The report candidly acknowledged that some of its assumptions may have reduced the reliability of this estimate, noting that it took hospital charges to reflect true resource costs and ignored both indirect economic effects and "potential savings attributable to averted medical expenses" incurred in caring for a dying patient (ibid.: 29). The report's completeness and candor on these points were unprecedented; they serve to highlight the shortcomings of other prominent studies and the great need for better data gathering (ibid.: 30).

The LTTF's average total cost figure obscures the possibility that the marginal or incremental cost of a transplant may be considerably less. Based on the observation that transplantation could be undertaken in Massachusetts hospitals without adding equipment or personnel, the LTTF concluded that hospitals undertaking transplantation should be required to do so within their respective current cost ceilings under Massachusetts's system for regulating hospital revenues (ibid.: 39–40). Under this recommendation, a hospital could receive no additional funds by virtue of adding a liver transplantation program and would thus have to finance its involvement from any surpluses it might earn or by economizing on (or terminating) the provision of other services. It appears that the LTTF judged liver transplantation to have so little proven value to date that new public or private outlays for it were not warranted. A payment restriction was one of several methods by which the LTTF hoped to achieve a "controlled dissemination of liver transplantation in Massachusetts" until more data on its efficacy, cost, and desirability were collected (ibid.: 35).

Although this decisive call for caution seemed to stem from strong reservations about the value of the new technology, the Fineberg report stopped short of addressing the most fundamental question raised in its charge. Admitting great discomfort in addressing the question of whether liver transplantation should take place at all, the LTTF passed the buck. Declaring itself "not legitimately constituted to render these views on behalf of society" (ibid.: 31),[11] the LTTF asked the commissioner of public health to "appoint a broadly representative advisory body to consider the difficult value judgments about whether society can and should support liver transplantation and to what degree" (ibid.: 42). Hidden in this response, it should be noted, is an affirmation of the assumption that a single choice for "society" as a whole is necessary and appropriate and that this choice should be made by a committee in the first instance and ultimately by political processes. By recasting the question to focus on whether society should "support" trans-

11. The LTTF's reservations about its competency were based on the fact that it was composed predominantly of scientists.

plantation, the LTTF seemed to eliminate the possibility that transplantation would be expressly forbidden. It is also possible, however, that the LTTF simply recognized that the regulatory blanket covering Massachusetts hospitals was so stifling that a decision not to "support" transplantation was tantamount to prohibiting it.

The regulatory setting. The specific occasion for creating the LTTF was an application by New England Deaconess Hospital to the Department of Public Health for an exemption from state DON requirements that would allow a small number of liver transplants in 1983.[12] On further inquiry, the department found that Massachusetts General Hospital, Children's Hospital, and the New England Medical Center were also prepared to perform liver transplants.[13] It was hardly surprising that Boston's internationally prominent research hospitals were eager to perform liver transplants after the publicity given to Jamie Fiske's ordeal.

Like those of other states, Massachusetts' certificate-of-need program (known as DON) makes capital expenditures and substantial changes of service subject to approval by state authorities.[14] Such regulatory programs, the adoption of which was at one time required by federal law,[15] were established in an effort to curb the proliferation and expansion of health care facilities so that growth would correspond to officially projected needs.[16] The Massachusetts DON statute and regulations give especially broad authority to the Department of Public Health to determine whether a "substantial change in services" is needed,[17] and it was apparently conceded that a liver transplantation program needed state approval under this provision. The immediate reason for commissioning the Fineberg report was to assist the department in the DON process (Task Force 1983: app. B). Without affirmative action by the commonwealth, Boston's research hospitals would be barred from performing liver transplantation.

For interested hospitals, getting a DON was only the first regulatory hurdle. Massachusetts places a ceiling on hospital expenditures through its "all-payer" maximum allowable cost (MAC) system.[18] Under this system of revenue limits,

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12. See letter from Frechette to Fineberg, *supra* note 9. Several interviews confirmed the identity of the institution in question.

13. These four hospitals supplied the LTTF with much of its information about the feasibility of liver transplantation in Massachusetts (see Task Force 1983: app. D).

14. Mass. Gen. Laws Ann. ch. 111, § 25B (West 1977).

15. The Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 93 Stat. 606 (1974) (codified in scattered sections of 42 U.S.C.), made the availability of certain federal funds conditional on the enactment of a certificate-of-need program meeting certain standards. The federal compulsion has recently been relaxed (see Alpha Centerpiece 1986). Pending legislation would make state participation voluntary (see Congressional Quarterly Weekly Report 1986).

16. On the policy underlying certificate-of-need laws, see Havighurst (1973, 1982), and Bovbjerg (1978).

17. Mass. Gen. Laws Ann. ch. 111, § 25B (West 1977); Mass. Regs. Code 105, § 100.020 (1977).

18. The MAC system was put into place by chapter 372 of the Massachusetts Acts of 1982; see

each acute care hospital's annual operating budget ceiling is determined in advance by the state, and the hospital is then permitted to collect revenues necessary to cover its anticipated needs from Medicare, Blue Cross, and private insurers, roughly in proportion to the number of beneficiaries treated.[19] Instituted in 1982, the MAC program assures each hospital prospectively that it will receive payments reflecting its actual 1981 costs plus adjustments for inflation, exceptions, and certain other factors.[20] The provision for exceptions permits a hospital to seek additional revenues to cover the anticipated costs of approved new services, such as liver transplants, and capital and operating expenses associated with other DONs.[21]

Naturally, any hospital receiving a DON to begin performing liver transplants would also wish to receive payment for them under a MAC exception. Under the Fineberg report's recommendation, however, the exception would not be granted and the hospital would have to finance the service out of savings elsewhere. Under these circumstances, a transplant candidate with an insurer willing to pay for the procedure might not find a Massachusetts hospital willing to provide it, because any hospital revenue from treating that patient would have to be offset by reduced revenue from treating others.[22] On the other hand, a MAC exception would allow the hospital to cover the costs of transplants by cost shifting, increasing its charges to the various payers in order to pay for transplants needed by patients lacking adequate insurance.[23]

Under these regulatory circumstances, the willingness or unwillingness of payers to pay for, or of patients to buy coverage for, such procedures would have little or no effect on whether transplants would be undertaken. This decision was essentially the state's, and if the state decided to authorize the service, the public would pay for it one way or another. But this payment would not necessarily be through the usual method of openly levying taxes and explicitly appropriating funds for worthy public projects. The Massachusetts philosophy, with which no one seems to have quarreled throughout this episode, is apparently that the state

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Mass. Gen. Laws Ann. ch. 6A (West Supp. 1985). It established a prospective payment system for Medicaid and private insurers, modeling the approach after a Blue Cross hospital payment contract already in use. A federal waiver made the state's payment system binding on the Medicare program. *Id.*

19. See Mass. Gen. Laws Ann. ch. 6A, §§ 50–56 (West Supp. 1985).

20. *Id.*

21. *Id.*

22. Freezing the resources available to an institution places responsibility for allocating those resources on the institution and its physicians. Decisions may not reflect the public's priorities because internal institutional politics allow economic interests and professional values to enter the picture (see Harris 1979).

23. The MAC system effectively breaks most of the links between the private insurance coverage that individuals buy and the care they receive. Hospitals are free to provide any of the myriad of services authorized by their DON and to tax the cost proportionately to all payers, up to the MAC limit (see *supra* note 22).

alone, through the DON/MAC process, should finally dictate such matters. The state's potential role in frustrating transactions between a willing buyer and a willing seller was not commented upon. As will be seen, the state was comfortable with—though perhaps not entirely comfortable in—its role as giver or withholder of lifesaving medical treatment.

The political scene. It is a widely noted fact of our political life that when an individual human life is placed in visible, media-covered jeopardy, a tug on the public heart strings loosens governmental purse strings, causing expenditures to save that "identified life" which far exceed what government is willing to spend to save an otherwise comparable "statistical life."[24] This phenomenon of our media-driven democracy can be viewed in contrasting ways. It is either, on the one hand, an inexcusable pandering to public passions by public officials freely using public funds to establish that they are compassionate and deserve reelection or, on the other hand, a healthy and reassuring affirmation that the community prizes each individual and is not coldly calculating when human life is at stake. Although such seemingly inefficient expenditures may be defensible because they give the community a chance to feel good about itself, it is also possible that they cultivate false impressions and divert attention and resources away from unfulfilled obligations.

Jamie Fiske's story had poignant consequences nationwide and illustrated the dilemmas that government faces in allocating public resources to health care in a political environment that demands concern for a handful of identified lives. Following Jamie's transplant, public and private financing mechanisms across the country faced strong public pressure to cover the costs of the procedure for other individual victims, frequently children (see Friedman and Richards 1984: 79; Wessell 1984: 1; Rust 1983: 1). The pressure was particularly acute for state Medicaid programs; a number of governors and legislatures responded by issuing ad hoc directives to finance highly publicized cases with state funds. In Missouri, for example, the legislature specifically authorized an exceptional payment on behalf of a 16-year-old girl, only to reverse itself the following week when two things happened: additional candidates appeared, demonstrating that one costly symbolic act would not be enough to satisfy the media, and perhaps consequentially, such private legislation was found to violate the state constitution (Friedman and Richards 1984).

Nowhere was the political pressure on a Medicaid program greater than in Massachusetts—the home of Jamie Fiske, as well as a major center for biomedical research and a state that had gone very far in accepting political responsibility for the operation of the health care enterprise. Massachusetts Medicaid declared liver transplants reimbursable for eligible persons in the summer of 1983. From then

24. See *supra* notes 2 and 4.

until January 1984, Massachusetts was in the anomalous position of guaranteeing to the very poor an extremely costly medical procedure that was not available to middle-class MBCBS subscribers. Thus, taxpayers were forced to buy for others transplants which they had not yet chosen to purchase for themselves through insurance. Although MBCBS was also under pressure, it was able as a private entity to hold out longer. This experience seems to confirm that elected officials and programs accountable to them—even more than private nonprofit organizations that strive to be perceived as benign dispensers of good things—do indeed seize opportunities to demonstrate their compassion by spending scarce public funds irrationally.[25]

Undoubtedly, Medicaid dollars allocated to transplants could have been put to better use in saving statistical lives or purchasing "quality-adjusted life years."[26] In California, the point was illustrated most tellingly: the legislative decision to pay for liver transplantation came at the same time that the legislature decided to terminate state support for its medically indigent population, those who cannot afford insurance for their own health care but are not deemed poor enough to warrant public assistance (Wessell 1984). The eagerness of public officials to gain credit for their humanitarianism, especially when someone else's money was at stake, was revealed even in the White House, which made a number of dramatic appeals to state governments and private payers on behalf of particular individuals (ibid.; Iglehart 1983; Meyer 1984). These scenes of elected representatives crowding onto the stage of this morality play left to the audience's imagination the effects of government policies on those who lacked the limelight.[27]

The private sector: MBCBS. Just as the public sector felt pressure to finance transplants for identified patients, private insurers all over the country, particularly Blue Cross plans, found themselves making difficult case-by-case decisions in full view of the media. MBCBS's particular problem in this regard was not solved by the continued failure of Massachusetts regulators to authorize transplants, because

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25. One report asserts that this pattern is not universal, and suggests that public insurers are on the whole reluctant to cover expensive new technologies (Evans 1986: 5). As the Missouri experience suggests, government's largess will stop when the costs to policymakers exceed the political benefits of being associated with a lifesaving effort.

26. Expanding Medicaid eligibility and coverage of preventive services would be obvious strategies (see, e.g., President's Commission 1983, which discusses what ought to be encompassed by "an adequate level of health care" available to all citizens and highlights current problems in health services delivery). On the use of "quality-adjusted life years" as a way of assigning priorities to public investments in health and safety, see Zeckhauser and Shepard (1976: 5, 11–15).

27. In yet another demonstration of elected officials' felt need to "do something" to respond to media attention to the transplantation issue and to get media attention for themselves, the Massachusetts legislature, in late 1983, added a check-off box to the state's income tax returns so that taxpayers could direct that a portion of any tax refund go into an organ transplantation fund. In 1985, when the check-off first appeared on tax forms, some 37,000 taxpayers contributed approximately $187,000 to the fund, which will probably be used primarily to help pay for cyclosporine and other follow-up care for transplant recipients (interview with Joan Gorga, Department of Public Health, Boston, July 1985).

insureds could still request treatment out of state. For this reason, MBCBS did not oppose the effort by local hospitals to get DON approval for transplantation. Indeed, MBCBS took the view that if it was going to have to pay for transplants eventually, it would be better to pay for in-state procedures.[28] It anticipated that the MAC system would control the incremental cost and that the DON system would limit the number of facilities.[29] Together these regulatory programs might restrict the capacity and the incentives of the system to perform more than a few procedures.

For the time being, however, MBCBS was reluctant to accept responsibility for paying for liver transplants anywhere. According to MBCBS officials, public pressure to pay for liver transplants in 1982 and 1983 was enormous. Although they did not wish to be perceived as denying potentially beneficial care, however costly, to any insured,[30] the plans were also hesitant to waive the contractual limitation under which they were obligated to pay only for generally accepted medical procedures. One reason for this attitude was recognition of the financial cost which transplants would impose on them immediately and which would have to be built into future premiums charged to customers already grumbling about high insurance costs (Wessell 1984).

Another explanation, however, had to do with MBCBS's view of its precise role in the Massachusetts system. MBCBS complained that it was not getting clear signals from its usual sources. On the one hand, there were the pressures from the media and the example set by the Medicaid program. On the other hand, the health care system's central decisionmakers were not speaking with one authoritative voice (Rust 1983).[31] For example, in 1982 and 1983, although liver transplants were gaining favor, MBCBS's medical advisors could not reasonably declare liver transplantation to be accepted therapy covered by their policies because any reasonable chance of a procedure's success depended upon use of a drug, cyclosporine, which the U.S. Food and Drug Administration (FDA) considered experimental until September 1983.[32]

Apparently wedded to a vision of themselves as mere financing intermediaries bound to give effect to any doctor's prescription made according to policies centrally determined by professional and governmental decisionmakers,[33] MBCBS

28. Interviews with Douglas Dickson, ombudsman, and James Young, M.D., medical director, Massachusetts Blue Cross, 15 July 1985; see also Rust (1983).

29. Interviews with Douglas Dickson and James Young, 15 July 1985.

30. Interviews with Douglas Dickson and James Young, 15 July 1985.

31. The termination of the National Center for Health Care Technology in a 1981 funding cut left MBCBS and other third-party payers without the prospect of an authoritative government opinion on which to base their payment decisions.

32. HHS News, pub. no. 83-19, 2 September 1983.

33. For complex reasons, private health insurers have long denied responsibility for influencing providers' treatment decisions, relying instead on professional or governmental decisionmakers to establish what services should be paid for (see Havighurst 1988).

preferred to rest coverage decisions on the actions of public regulatory agencies such as the FDA. It thus resisted any suggestion that it should embark on independent assessments of medical treatments, either paying for something officially deemed experimental or refusing on benefit/cost grounds to pay for something that enjoyed professional and governmental approval. As nonprofit corporations together constituting the dominant health insurer in Massachusetts, MBCBS plans were dependent on the public's perception of them as a benign source of financial assistance in meeting officially recognized medical needs. The Blues were beginning, however, to see the high cost and difficulties of marketing themselves in this way.

In mid-1983, MBCBS's arguments for not paying for liver transplants began to collapse. In May, the Fineberg report called liver transplantation "clinically justifiable" (Task Force 1983), and in June, a National Institutes of Health consensus conference stated that "liver transplantation offers an alternative therapeutic approach which may prolong life in some patients" (NIH 1983). When these lukewarm semi-official endorsements of liver transplantation were combined with media attention to the plight of transplant candidates and the relative willingness of other insurers and Medicaid to pay for liver transplants, they seemed to leave MBCBS with no choice. MBCBS had to discover some way around its own guidelines or be perceived as denying treatment solely because of the procedure's high cost. The solution that MBCBS hit upon was to offer its subscribers a transplant insurance program, called "TIP" (Rust 1983: 16–17). By this means, it hoped to bridge the gap until the FDA would approve cyclosporine, which would allow MBCBS, consistent with its principles, to build transplants into its basic coverage and rates.

TIP was a separate, optional rider offered to all employment groups or "accounts" at a cost of 55 cents per individual or $2 per family per month. TIP offered full coverage for heart, heart/lung, and liver transplants, beginning five days before the procedure and continuing for twelve months thereafter.[34] If an account chose to purchase TIP, it would be mandatory rather than optional for the account's insureds or "members." Before offering TIP, Blue Cross conducted several opinion surveys to determine whether the public pressure it was feeling would actually translate into individual choices to purchase transplant insurance. These surveys indicated considerable desire for such insurance on the part of surveyed individuals and families.[35] However, the response to TIP itself differed significantly from the response to the surveys.

TIP was offered to MBCBS accounts in September 1983. Although John Larkin Thompson, president of Blue Shield, called TIP "the ultimate referendum on

34. Blue Cross and Blue Shield of Massachusetts mailing to accounts, "Special Announcement: New Transplant Insurance Plan," September 1983.

35. Interview with Douglas Dickson, 15 July 1985.

whether or not the public wants to pay for these operations" (Rust 1983), TIP was not offered directly to individual members because MBCBS feared the effects of adverse selection.[36] It was left to employers to act for their insured employees. Conceivably, publicity given to the transplant issue placed employers in a political position vis-à-vis their workers that was not dissimilar to that of MBCBS and Medicaid vis-à-vis the larger public. Not wanting to appear to economize at the expense of employees who might need a transplant, employers may have been more willing to buy TIP than the employees themselves would have been. On the other hand, employers might be reluctant to buy transplant coverage because its cost might be perceived as difficult to pass on to employees.

Each account was sent a special announcement explaining TIP, which stated, "The public has indicated its desire to have coverage for organ transplants."[37] The announcement was clear and complete, but gave accounts only about a month to make a decision whether to begin TIP coverage on 1 November. It left them, however, the alternative of picking it up at their regular renewal period during the next calendar year.

The TIP "referendum" was never completed because MBCBS discontinued it as of 1 February 1984. Cyclosporine had actually received FDA approval in September 1983,[38] and in January 1984, MBCBS's medical advisory committee finally recommended that liver, heart, and heart/lung transplants be considered medically accepted procedures. These developments allowed transplantation coverage to be extended to all accounts, with a premium increase roughly equal to the TIP premium.

In contrast to the results from MBCBS's preliminary surveys, TIP did not prove especially popular during its brief marketing. By the time it was discontinued, only 7,400 of the 24,348 accounts to which it was offered had purchased the coverage, 7,100 had refused it, and the rest—over 9,800—had not responded (Friedman and Richards 1984: 79). Even the Massachusetts Commissioner of Insurance, who had statutory responsibility to act as the account decisionmaker for MBCBS's 120,000 nongroup subscribers (including a special group of low-income individually insured), had failed to make a decision regarding TIP before it was mooted.[39] There are many possible explanations for the modest response rate. Some accounts may have intended to pick up TIP when they next renewed their coverage. According to MBCBS, however, financial considerations probably loomed largest in accounts' decisionmaking. In addition, some accounts, particularly large ones based in more than one state, may have preferred to pay for transplantation in different ways so as to be able to offer uniform coverage to employees in all states.

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36. Interview with Douglas Dickson, 15 July 1985; interview with Dorris C. Commander, underwriting manager, Blue Cross of Massachusetts, July 1985.
37. Blue Cross and Blue Shield mailing, *supra* note 34.
38. HHS News, pub. no. 83-19, 2 September 1983.
39. Interview with Douglas Dickson, 15 July 1985.

One employer, Honeywell, wanted the opportunity to approve the transplanting facility.[40] MBCBS was much more interested in seeing that someone other than itself, preferably the state through DON, would be responsible for approving facilities and quality control.[41]

At MBCBS, there was little surprise at TIP's poor showing, and the perceived reason for it was TIP's cost. Yet no thought was ever given to making a point of the public's apparent indifference to transplant insurance once an actuarially fair price tag was attached. Perhaps MBCBS saw no difference from a public relations standpoint between denying transplants on the ground that the procedure was experimental and telling an individual that because his employer had rejected the TIP offer, he could not have a lifesaving procedure that the plan was providing for others.

In any case, MBCBS made no real effort to examine and ponder the significance of the TIP experiment. Indeed, it was quite happy to extend its regular coverage to handle transplants. TIP had been complicated and cumbersome. Because it constituted a separate insurance program with a separate pool of funds, TIP required a lot of tracking to separate costs attributable to the transplant from ordinary medical costs. This tracking difficulty led, in part, to the "five-days-before, twelve-months-after" policy under which all medical costs incurred within that period were deemed attributable to the transplant. Both this policy and, later, the demise of TIP sacrificed Blue Cross's ability to extract easily any data on transplants. All transplant data now go into the files with every other medical procedure and, as such, are entered per hospitalization rather than per individual insured; cumulative information on rehospitalization, outpatient care costs, and related other costs are difficult to retrieve.[42]

Although apparently efficient, blending transplant coverage into a system geared only to paying claims and not to evaluating the costs and benefits of particular procedures may be a false economy. It is, however, a predictable feature of a health care system in which private insurers such as MBCBS perceive themselves merely as executing orders from the top. MBCBS throughout this episode seemed troubled only that it was unable to interpret the conflicting signals it received. Once transplants crossed the threshold of acceptability at the FDA, the NIH, the LTTF, and the DON agency, the Blues could go happily back to their usual business of forcing consumers to buy things that they have had no real opportunity to refuse.

Enter the Task Force on Organ Transplantation. The foregoing events left Massachusetts about to plunge into transplantation. Yet a number of problems still existed; these resulted primarily from the way in which the DON and MAC pro-

40. On Honeywell's transplant coverage, see Minnesota Coalition (1984: 48) and Utah Health Cost Management Foundation (1985: 3).

41. Interview with James Young, 15 July 1985.

42. Interview with Dorris Commander, July 1985.

grams were articulated. Simply granting a DON without increasing the MAC allowance, as recommended by the Fineberg report, would give rise to the danger that hospitals, instead of cutting back on indisputable waste to finance transplants, would terminate other, more essential services, creating problems throughout the system. For example, a hospital closing a maternity service and using its MAC allowance to start transplants would leave its obstetrical patients to burden other hospitals, which could not be assured of increased MAC allowances to provide for these patients. In this way, the threat of sudden introduction of a costly new therapy revealed major flaws in the state's basic faith that hospitals' revenue needs could be predicted by a formula without creating major anomalies, windfalls, and unfairnesses.

The liver transplant challenge also revealed faults in the regulatory system. Simply granting a MAC exception on the theory that transplants had now become just another accepted therapy would mean losing the opportunity to ensure that the procedure was being used appropriately and that information on its safety, efficacy, and cost would be available for subsequent appraisal. The six-figure price tag for each procedure made it clear to everyone that letting the system treat liver transplants as it treats virtually everything else had significant fiscal implications. Of course, it occurred to no one to question publicly whether letting the system freely prescribe high volumes of other treatments with five-, four-, three-, and even two-figure price tags might also be socially inappropriate or wasteful. Thus, the basic belief that doctors and hospital employ their limited resources rationally and in accordance with public objectives, a faith on which the entire regulatory system was built, was not challenged.[43] Instead, it was concluded only that the transplant issue, because it has met the public eye and could not politically be ignored, had to be addressed with greater particularity. Why the system could not be trusted here, when it was trusted to make virtually all other choices, was never made clear.

The need to control transplants specially loomed so large that another commission, the Task Force on Organ Transplantation (OTTF), was appointed. This new task force had a broader scope than the earlier one. It was charged with making policy for heart and heart/lung transplants as well as livers.[44] It was also asked to provide a social evaluation, not just a technical report. As the next act of our morality play will show, the OTTF was equal to the challenge to pronounce on the largest questions of public policy in health care.

Act two

The OTTF was convened in October 1983 by the commissioner of public health under the chairmanship of George Annas of the Boston University School of Public

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43. See notes 22 and 23.

44. The OTTF's report was unclear why transplantation of bone marrow, kidneys, and other organs was not treated as well, but in stating that liver and heart transplants were "the [only] ones currently clamoring for wider introduction," the OTTF confirmed that its inquiry was shaped by politics, not by a desire to rationalize the provision of all expensive medical care (Massachusetts Task Force 1984).

Health. It was charged "with the development of standards and processes for evaluating the use of organ transplantation (Massachusetts Task Force 1984: 3, 119). The question expressly left unanswered by the Fineberg report—whether transplantation should "be encouraged or [even] permitted"—was not even raised: "The work of the Task Force can be categorized in terms of the when, who, what and how of organ transplants" (ibid.: 119). Although the OTTF did hear testimony on the issue during its meetings,[45] the objections raised concerning whether to proceed with transplantation at all did not detain OTTF members long.[46] The political climate obviously precluded a firm stance against the new technology.

The OTTF's report, the recommendations of which were unanimous, was released in October 1984, although preliminary recommendations were released in January.

The OTTF's recommendations. The OTTF's first recommendation advocates the introduction of liver and heart transplantation "in a controlled, phased manner that provides the opportunity for effective evaluation and review of its clinical, social, and economic aspects by a publicly accountable body after an initial phase of 2–3 years of limited transplantation" (Massachusetts Task Force 1984: 10). This position, which sounds and may well have been, under the circumstances, eminently reasonable, was almost certainly inevitable, given the political impossibility of saying no to transplants. The OTTF, like the LTTF before it,[47] was clearly seeking a middle ground that would accommodate the pressure to allow transplants but not open the door to unlimited spending on the new technology. The recommendation of a later evaluation was necessary to preserve the appearance that the procedure was still in an investigatory or probationary stage. As the Fineberg report had noted, however, it is hard to stop a program once it has begun (Task Force 1983: 36).

The OTTF conveyed the impression that its unanimous conclusions were reached by rational planning, deep thinking by academic experts, and a collective social conscience. There is also the possibility, however, that it was simply compromising conflicting views, accommodating political pressures, and rationalizing the result. Although the charge that the OTTF's actions were in fact "political" might be taken as a criticism, many in Massachusetts would no doubt say that because the conclusions flowed from an open process and a representative body, the legitimacy

45. Alan Sager of the Boston University School of Public Health argued before the OTTF on 31 October 1983 that "all citizens of the Commonwealth should have euqal access to all effective care now routinely available before the range of therapies is expanded."

46. Interview with George Annas, OTTF chairman, July 1985. The recent report of the National Task Force on Organ Transplantation, created by the National Organ Transplantation Act, Pub. L. No. 98-507, 98 Stat. 2339 (1984), does not address this issue, simply assuming that transplantation of all kinds should be covered by public and private financing programs (U.S. DHHS: 1986). The Minnesota Coalition report, noting the trend to converge, recommended that it "should remain optional for group accounts"; no opinion was expressed on public plans' policies (Minnesota Coalition 1984: 47–48).

47. See text accompanying note 10.

and soundness of the result and of the values promoted are unchallengeable. Whether such faith in the politics of interest-group liberalism is warranted should be regarded as an open question, however,[48] and indeed it is one of the central questions inspiring this appraisal.

The OTTF's second recommendation elaborates on the first by emphasizing that transplantation should not be made "generally available" until after the recommended review by a "publicly accountable body," which should not be limited to assessing the technology's status as "experimental" or otherwise (Massachusetts Task Force 1984: 11). The report also makes clear that in the task force's view, availability is synonymous with general reimburseability (ibid.: 11–12). It opines, too, that general availability should not result only through the state Medicaid program's becoming "the de facto insurer for all such procedures" (ibid.), by virtue of inadequate private financing and the impoverishment of transplant candidates. To prevent this result and to "ensure fairness in the distribution of burdens regarding reimbursement," the report suggests that coverage be prescribed by a "joint committee" of government representatives and private insurers (ibid.). Such a body might violate the federal antitrust laws, however, unless its decisions were embodied in official government action.[49]

Recommendations (3) and (4) by the OTTF introduce the issue of costs. During the evaluation period, authority to do transplants would be granted only to those hospitals that agree to perform them within the MAC, with an exception for each procedure that amounts to the costs of organ procurement and cyclosporine (ibid.: 14).[50] This attempt to force hospitals to finance a portion of the cost of transplant programs by economizing was apparently the only way, even in this heavily regulated state, in which the volume and hence the overall cost of transplants could be kept down. To protect against the concomitant risk that transplantation would displace other vital services, recommendation (3) suggests that need determinations in the DON program be made only upon a showing that the cost of adding transplantation can be borne without sacrificing more desirable services. "As a principle, the Task Force believes that if it turns out that liver and heart transplantations take resources away from higher priority health care services, and decrease their accessibility to the public, then transplantation procedures should not be performed" (ibid.: 13).

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48. Cf. Havighurst (1980) (disputing claims by a Massachusetts advocate of regulation that politicized regulation is legitimized by the democratic process and should be immune to general criticism).

49. In general, the Sherman Act, 15 U.S.C. § 1 (1983), prohibits collective actions of the kind that are taken for granted in centrally governed health care systems as a useful adjunct or alternative to direct governmental control. Although the McCarran-Ferguson Act, 15 U.S.C. § 1001 (1983), provides a partial exemption from the Sherman Act for "the business of insurance," an agreement not to sell a certain type of coverage has been held to fall within an exception to this exemption. St. Paul Fire & Marine Ins. Co. v. Barry, 438 U.S. 531 (1978).

50. Such costs would amount to about $9,000 per heart transplant and $44,000 per liver (Massachusetts Task Force 1984).

In a section antecedent to its specific recommendations, the OTTF gives its final word on how to prevent a modest amount of costly transplantation from diverting resources from essential services:

> The Task Force believes that these procedures should be performed on [all] those who are likely to benefit from them, so long as the total cost is controlled, and resources are not diverted from higher priority medical procedures to liver and heart transplantation. The question of what a "higher priority" procedure is will be based on the total number of individuals affected, and the importance to their lives of the intervention. For example, it *may* be appropriate to shut down an underutilized maternity program to do organ transplants. The burden of demonstrating that such a tradeoff is appropriate, however, should be on the hospital proposing it. Accordingly, in the [DON] process, all currently available health care services should be presumed to be higher priority than transplantation. The applicant should have the burden of demonstrating that transplantation has a higher priority than any other currently available health care service from which organ transplantation diverts funds and/or support systems (ibid.: 9, 10).

Such an allocation of the burden of proof would apparently require a hospital to prove its own past inefficiency and waste of public resources in order to qualify for the establishment of a transplant program; a well-run hospital doing only things highly beneficial to patients need not apply. Such paradoxes are common under regulation. Perhaps the crowning irony, which the task force itself notes in its chapter on costs (ibid.: 60), is that transplantation can be contemplated in Massachusetts only because much of its high cost can be paid out of waste in the system—the very thing that regulation was supposed to prevent. The presumption that the OTTF created against the displacement of existing services by transplants can hardly be taken, in context, as an expression of faith that regulation has in fact achieved true efficiency.

Recommendation (5) addresses patient selection criteria and would require them to be "public, fair, and equitable" and based initially on medical suitability criteria and secondarily on the principle of first-come, first-served, in the event demand exceeds the supply of organs (ibid.: 16–17). For Massachusetts residents, the ability to pay should not be a factor, nor should social class or family support (ibid.). The report suggests an "appeal mechanism" to ensure fairness, thereby conjuring up a vision of two lawyers advocating their dying clients' competing claims to a single liver before a neutral decisionmaker. This is a particularly striking example of how far the OTTF would go to ensure that the state appear legalistically fair in dispensing life and death.[51] With almost equal plausibility, the report could

51. For warnings of the consequences of excessive "due process" in dealing with sensitive issues of this kind, see Blumstein (1976: 231) and Havighurst, Blumstein and Bovbjerg (1976: 155–57). For

have required that patient selection reflect "affirmative action" aimed at redressing past societal injustices toward certain groups.

Finally, recommendation (6) introduces the idea that heart and liver transplants in the commonwealth should be undertaken by hospitals belonging to a consortium organized to share data, experience, and resources (Massachusetts Task Force 1984: 18–20). This idea apparently did not originate with the OTTF because it stated that there is no economic justification for beginning organ transplantation at more than one hospital, but that if more than one hospital is to do the procedure, there must be a truly integrated and cooperative effort—a "worthwhile consortium" (ibid.). The consortium concept had appeared earlier in a staff recommendation by the Department of Public Health in connection with the pending DON application (ibid.: app. B). In addition, the consortium idea was dictated in part by the state's refusal to grant a MAC exception, thereby drastically limiting the number of procedures that any one institution could afford to perform.

Use of several institutions put the regulators on very shaky ground, however, in light of another prime goal of regulation—ensuring the quality of care. Because it is widely accepted that experience improves outcomes, the Department of Public Health could have been criticized if it authorized several hospitals each to perform less than the optimal number of procedures per year. The consortium concept, if it allows experience truly to be shared, overcomes this objection.[52] Its adoption in Massachusetts, however, appears to have been only a face-saving compromise, necessitated by the political unpopularity of giving all the business to one institution.[53]

The consortium approach solved problems for a number of the participants in the drama. The consortium idea was initially attractive to the Department of Public Health because it would relieve it of the politically difficult task of choosing among powerful institutions. MBCBS, which took credit for planting the seed of the consortium concept, was probably hoping to avoid having to select among or oversee competing hospitals or to adopt its own patient selection criteria.[54] The four hospitals seeking authority for liver transplants had figured out for themselves the advantages of a united front both in seeking a DON[55] and in avoiding possible future competition.

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scholarship approving the legalistic approach, see Katz and Capron (1975: 239–40, 246–48) and Yale Law Journal (1975).

52. A factitious consortium, however, could result in significantly poorer patient outcomes. This reasoning was the substance of an ultimately unsuccessful challenge mounted by the OTTF's chairman to the later-proposed Boston heart consortium. See brief for appellant at 10-13, George J. Annas Ten Taxpayer Group v. Department of Public Health (Health Facilities Appeals Board argued 9 July 1985) (project no. 4-3306).

53. George Annas (1985a: 4–5) has described the consortium concept as "primarily a political issue . . . grafted onto the original draft of the Report at the request of the Commissioner of Public Health."

54. Interview with James Young, 15 July 1985.

55. Some members of the OTTF viewed the consortium concept with suspicion, considering it an

The egalitarian motif. Perhaps the most notable feature of the OTTF report is its strong emphasis on equality in the distribution of transplanted organs. Perceiving this as the central question in the morality play, the task force declaimed:

> On the issues of equity and fairness, we concur with the conclusions of the President's Commission for the Study of Ethical Problems in Medicine: society has an ethical obligation to ensure equitable access to health care for all; and the cost of achieving equitable access to health care ought to be shared fairly. *Transplantation of livers and hearts should therefore only be permitted if access to this technology can be made independent of the individual's ability to pay for it,* and if transplantation itself does not adversely affect the provision of other higher priority health care services to the public (Massachusetts Task Force 1984: 9–10).

A literal reading of the italicized lines indicates that the OTTF not only endorsed the provision of transplants to those who cannot afford them, but also took the startling position that paying patients should be denied transplants in Massachusetts until such time as every equally needful patient could get one. As noted earlier, it is easily within the power of Massachusetts regulators—without actually making the performance of this therapeutic procedure a criminal act[56]—to prevent a dying patient from purchasing a transplant with his own money from willing providers. The OTTF apparently approved the use of the state's prohibitory powers in this way in order to coerce a public desirous of transplants for themselves into providing them for everyone. Probably, however, the task force never expected that such extortionate use of the state's regulatory power would actually be necessary to effectuate its policy objective of equity in transplantation.[57]

Although the OTTF may not have meant what it said about withholding transplants from paying patients as an inducement to the procedure's equitable provision, the OTTF was clearly unresponsive to the interests of those citizens who would not require the state's assistance to finance a transplant. Under the report's recommendations, transplants will occur only on the state's own terms, and only a limited number of transplants will be performed, regardless of the availability

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end run around the DON process that permits four programs rather than just one to perform transplants and makes it easier for the hospitals to demonstrate that other services are not being displaced. Cf. brief for appellant, *supra* note 52, at 9–10 (makes this argument with regard to the proposed heart transplantation consortium).

56. Outright state prohibitions of therapeutic procedures can raise a constitutional issue. E.g., Roe v. Wade, 410 U.S. 113 (1973) (abortion); Rogers v. State Board of Medical Examiners, 371 So. 2d 1037 (Fla. Dist. Ct. App. 1979) (chelation therapy). Regulatory programs having comparable effects are more difficult to challenge legally but should raise similar concerns.

57. The DON for the liver transplantation consortium had already been granted in January, and a heart transplantation DON was issued in May. Letter from Department of Public Health to Richard Nesson, Brigham and Women's Hospital, 16 May 1984, reprinted in Massachusetts Task Force (1984: 129).

of organs. Because recipients of these few procedures must be selected, some patients who could and would pay their own way will not get treated.[58] Yet, if they were allowed to purchase their own treatment outside the MAC system, there would be no diversion of resources from "higher priority" health care. The OTTF appears content with a state policy that could deny a transplant to a dying person who had made explicit financial provision for it. The best explanation for this complacency in the face of a denial of lifesaving medical care may be simply that the OTTF members had lost the capacity to conceive of the purchase of health services as a private matter. If so, their attitude reveals a great deal about the political culture of Massachusetts and its approach to health care.

Denouement. The OTTF report was received by the Public Health Council of the Department of Public Health and was the subject of a public hearing on 5 November 1984. The council unanimously adopted the report's recommendations as official policy and instructed the department to use the text of the report for guidance in DON proceedings. The current state of organ transplantation in Massachusetts appears to have followed the outlines of the OTTF's script. There are questions, however, whether the spirit of its recommendations has been observed in practice. For example, it is doubtful that hospitals seeking DONs for transplantation have given any real guarantee that "higher priority" services will not be affected. Also, it has been questioned whether the consortium is really functioning as an integrated research program dedicated to collecting useful data for later evaluation by a "publicly accountable body."[59] It would appear that the drama is not yet over.[60]

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58. The OTTF may have viewed this as only a theoretical danger. It may have expected, for example, that all medically defensible transplants would in fact be provided. Disagreement is likely, however, over whether a particular procedure is desirable or "indicated," and it is well documented that as a technology improves, the medical indications for its use broaden (see Caplan 1983: 23, 31). The OTTF also might have thought that anyone who could afford the procedure could also afford to travel out of state to get it. This proposition holds true, however, only if other states reject a Massachusetts-type hostility to transplantation and also permit outsiders to obtain organs and if the patient's ability to pay does not stem from the purchase of health insurance, which typically does not cover the many additional expenses associated with out-of-state treatments. Although the OTTF may have had reason to discount the risk that some self-supporting patients would be denied desired transplants, its report expressly recognizes that the number of people waiting for transplants might exceed the number of procedures that could be done. It is possible that it is simply not fashionable in Massachusetts publicly to express concern about the "right to health care" of anyone except the poor.

59. Both the OTTF and the Department of Public Health contemplated a later evaluation of the liver transplantation program to see whether higher priority services were being displaced and expected that the data collected would shed light on this issue, on which the consortium would have the burden of proof. The first annual report of the consortium, covering 26 January 1984 to 26 January 1985, was brief, even cursory, and seems not to contain the data required by the DON, let alone data that could prove anything about displacement (Boston Center 1985). Even the actual costs of transplantation per survival year are impossible to calculate from the report. Patients' rehabilitation status is only sketchily assessed, and no data are supplied as to the basis for rejection of candidates or the current health status of thos rejected (ibid.). Without comparative outcomes, it is impossible to judge the procedure's value

Reviewing the performance

Viewers of the morality play *Liver Transplantation in Massachusetts* must come away unsatisfied but instructed in the difficulties of putting life-and-death choices on the political stage. Perhaps more than any other state, Massachusetts, aided and abetted by a powerful intellectual community, has assumed the role of dominant decisionmaker in health care matters. The case of liver transplantation provides a unique test of the ability of at least one model of a monolithic, highly regulated, and politicized health care system to address difficult choices involving expensive medical technology.[61]

In the Massachusetts system, it was necessary for the state to decide publicly whether to allow liver transplantation at all, and the action of the drama was ostensibly about the making of this choice. Politically, however, the state probably never really had the option of rejecting transplants once major research institutions resolved to perform them and the media concluded that access to them was the right of every commonwealth citizen. As in a Greek tragedy, the outcome was foreordained, and the characters were never truly free to alter the inevitable results. It is in the nature of "tragic choices" that once they become political, they are driven mainly by forces beyond the power of individuals to control or escape.[62]

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or the predictive effectiveness of the patient selection criteria used. There is also no evidence that transplants have not displaced desirable services. Some OTTF members, including Chairman George Annas, argue that the coalition is violating at least the spirit of its DON (interview with Annas, July 1985). The Department of Public Health seems to feel, however, that because the data collection requirements for livers were never very well defined, the coalition's first report is satisfactory (interview with Joan Gorga, July 1985). At a recent conference, panelists discussing the Massachusetts system—including Public Health Commissioner Walker, transplant surgeon Roger Jenkins, OTTF chairman Annas, and economist Marc Roberts—disagreed in almost every particular regarding whether the department and the consortium were doing what they were expected to do (Conference on Transplantation 1985). The lack of agreement on a variety of issues suggests that the apparent consensus surrounding the OTTF report resulted from a failure to address practical issues and a papering over of potential problems. Indeed, at the conference just cited, OTTF chairman Annas labeled the OTTF "a quasi-Quixotic noble failure" (ibid.).

60. At present, however, the even more complicated debate over heart transplantation in Massachusetts is apparently diverting much attention from the liver issue (interview with Joan Gorga, July 1985). The parties to this debate are more experienced and sophisticated that they were at the time of the liver debate. In particular, Massachusetts expects to employ many of the recommendations developed by the Battelle Human Affairs Research Center (see Evans 1984).

61. See note 6. A particularly interesting point of comparison is provided by the Minnesota Coalition (1984) report, which, as the product of a private organization, is a much less political document than the OTTF report.

62. Keeping such issues out of the political arena is itself difficult. As a societal attempt to resolve the tragic choice by finessing it, this strategy, like others, is apt to be unstable precisely because it sacrifices important values, such as openness and explicitness. Calabresi and Bobbitt (1978: 195–99) predict an inevitable and continuing oscillation among imperfect solutions as society continually reasserts those values (equity, efficiency, freedom, etc.) that are being neglected by whatever system of choosing is currently in place. However, whether a stable system can be designed or happened upon without explicit policy choice is an empirical question. In any case, depoliticization would appear to be a vital first step toward possible stability.

To accept the decisions emerging from the black box of Massachusetts state government as appropriate societal choices is to ignore not only the previously noted questionable features of the political process, but also the shortcomings of regulation, some troublesome ethical issues, and the possible availability of alternative decisionmaking mechanisms.

Regulatory inadequacies. Having approved transplants in principle, the Commonwealth of Massachusetts and its respective task forces then had the problem of rationing the costly procedure. However, the Massachusetts regulatory scheme, despite its comprehensiveness and complexity, provided no public mechanism for deciding explicitly how often and under what circumstances the procedure would be done. As one protection against high costs, the task forces recommended against a complete pass-through of expenditures for transplants, thus forcing hospitals to look elsewhere for at least some of the necessary funds. Under the state's regulatory control of hospital revenues, virtually the only way for a hospital to generate such funds would be to cut back its other activities. The OTTF's response to the danger that transplants would displace more valuable hospital services was to instruct the DON agency to withhold approval of a transplantation program that could not prove that only relatively wasteful activities would be eliminated in order to accommodate it. As a regulatory standard, this requirement was highly impractical and unrealistic,[63] but it protected the task force against the criticism that it had authorized a diversion of resources to lower-priority uses.

With all their regulatory paraphernalia, Massachusetts officials lack the statutory powers they need to control directly the volume and cost of transplants. As to these and all other medical procedures, the state can only identify institutional providers of needed services and control, in a rough way, the total resources at each institution's disposal. Because these powers do not add up to effective control of medical technology, the level of transplantation activity in Massachusetts remains ultimately in the hands of prestigious doctors and hospitals, subject to certain resource constraints. Although limiting the resources available to providers can control aggregate costs, the Massachusetts MAC controls relate in no recognizable or rational way to the potential benefits or costs of any particular procedure. Allocational decisions are thus left in providers' hands.[64] Once Massachusetts is satisfied that the resources used in organ transplantation are not obtained by eliminating "higher priority" health services currently being provided, it permits transplants to proceed without regard to the additional possibility that those resources might have still other, more valuable uses.

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63. See note 59. Two critics of the OTTF's burden-of-proof recommnedation for DON proceedings have said, "It is difficult to imagine a process that is more conceptually confining, less amenable to empirical analysis, and more open to subjective interpretation" (Overcast and Evans 1985: 106).

64. See note 23.

Thus, although Massachusetts has made it appear that it has exercised statesmanlike control in this highly publicized area, it may have done nothing more than give certain Boston hospitals the green light to rearrange institutional priorities to facilitate new adventures on the frontiers of medicine. The main constraint on these institutions is the risk that their actions will offend future state officials or the "publicly accountable body" that the OTTF recommended to evaluate transplantation later on. The implicit threat that the state might take unspecified action in the future puts the participating institutions on notice that they had better be able to defend their use of resources or face unpleasant consequences. Such is life in a centrally managed health care system, where things fortuitously attracting public notice receive minute attention while well enough is left alone. Politicization of transplantation achieves control for its own sake but provides little assurance that resources will be put to their best use. A regulatory system that purported to make all the necessary allocational choices would be a more stifling form of regulation than even Massachusetts would be likely to tolerate.

Questions of values. Above all, Massachusetts strove for ethical high ground in establishing its position on liver and heart transplants. Yet a careful reading of state policy as reflected in the OTTF report reveals a willingness to countenance the denial of transplants to paying patients—not out of any paternalistic concern, but simply because some other person in comparable condition could not afford the same treatment. Perhaps it was the prospect of organ shortages and bidding wars that only the well-to-do could hope to win that induced the OTTF to approve the denial of transplants to paying patients. After all, the question of how to ration scarce medical resources has long inspired ethicists to philosophical debate,[65] and the OTTF, chaired by a leading participant in that debate,[66] may have assumed that it had been convened primarily for the purpose of prescribing an ethically satisfying system for rationing scarce organs.[67] The OTTF did not, however, expressly restrict its recommendations to situations where there were not enough

65. The relevant literature is voluminous. For general sources, each of which itself draws on many others, see Daniels (1985), Bayer, Caplan and Daniels (1983), Smith and Churchill (1986), and Childress (1978).

66. See, e.g., Annas (1979, 1985b, 1985c).

67. The OTTF's apparent eagerness to respond to that charge may be seen in its failure to consider seriously the possibility of encouraging the sale of organs by families of deceased potential donors to those awaiting transplants (Massachusetts Task Force 1984: 37). A market for organs would eliminate shortages and the need for rationing systems to allocate a limited supply. However, instead of seeking to break down the current cultural taboo against the buying and selling of body parts (see National Organ Transplantation Act, *supra* note 46), the OTTF took the easier political path. Indeed, it may have welcomed organ shortages as a constraint on the number of costly procedures and as an excuse for implementing their rationing theories (see, e.g., Massachusetts Task Force 1984: 80, 83). The shortage of organs is currently being addressed by donor education efforts, ranging from promoting the slogan "Organ Donors Recycle Themselves" to legislation requiring hospitals to request donations from families of potential donors.

organs to go around. As it appears, the OTTF was entirely comfortable with a policy that would force self-supporting transplant candidates to join (and perhaps die in) the state-mandated queue even if an adequate number of organs was available.

In support of its willingness to deny transplants to paying patients, the OTTF invoked a well-known 1983 report by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Although the President's Commission did declare that society has an ethical obligation to guarantee a decent level of health care to its neediest citizens,[68] nowhere did it indicate that it would be ethical to hold the wealthy and well-insured sick hostage without treatment until society honored this obligation. Moreover, the President's Commission clearly stated that it was not ethically necessary for all citizens to receive the same health care (President's Commission 1983). Thus, it certainly laid no foundation for the Massachusetts policy of forcing all transplant candidates to take their chances in a state-sponsored life-and-death lottery.

The OTTF again misrepresented the President's Commission in citing its report as authority for guaranteeing procedures as costly as liver and heart transplants to persons who cannot afford the insurance necessary to purchase them (Massachusetts Task Force 1984: 74). Although recognizing a public obligation to provide a decent minimum level of health services to all, the commission did not fully define that level or specify what services should be included in the guaranteed package. Moreover, there are numerous reasons why one might conclude that procedures as costly as liver transplants ought not to fall under society's guarantee until the nation becomes a great deal wealthier and has met a great number of other needs, including non-health needs, of its less advantaged citizens.[69] The OTTF seemed to conclude that the mere fact that transplants may save lives is enough to obligate society to pay[70]—despite the explicit finding that at $230,000

68. The President's Commission report states as its first premise that "society has an ethical obligation to ensure equitable access to health care for all," and continues, "Equitable access to health care requires that all citizens be able to secure an *adequate* level of care without excessive burdens" (President's Commission 1983: 4, emphasis added).

69. As the President's Commission explains, "The standard of adequacy for a condition must reflect the fact that resources used for it will not be available to respond to other conditions. Consequently, the level of care should reflect a reasoned judgment not only about the impact of the condition on the welfare and opportunity of the individual but also about the efficacy and the cost of the care itself in relation to other conditions and the efficacy and cost of the care that is available for them" (President's Commission 1983: 36). See notes 26 and 45.

70. The OTTF's conclusion that organ transplantation should be part of that adequate level of care is apparently justified by the stated public perception that transplantation is "life-saving" (Massachusetts Task Force 1984: 5). The president's commission report, however, does not contemplate and indeed does not seem geared toward addressing the inclusion of extreme and expensive technologies in the guaranteed minimum level of care. For example, it states, "Society will reasonably devote some resources to health care but reserve most resources for other goals. This, in turn, will mean that some health services (even of a lifesaving sort) will not be developed or employed because they would produce too few benefits in relation to their costs and to the other ways the resources for them might be used" (President's Commission 1983: 19).

to $340,000 per patient surviving one year, liver transplants were several times more costly than the most costly of other generally accepted medical treatments.[71] The OTTF thus backed itself into an ethically debatable position. While arbitrarily treating transplantation as being so valuable that it should be available to all, it also declared that because of the expense, only those transplants that could be financed primarily out of system waste should be provided. Thus, the OTTF's desire to demonstrate its and Massachusetts's commitment to providing lifesaving treatment for all led it to restrict transplants' availability to all patients, including those who would not require public financing. Such a policy had specifically been denounced by the President's Commission as "an unacceptable restriction on individual liberty" (President's Commission 1983: 4, 18, 20; Pauly 1985).[72]

Under the circumstances, it seems probable that the OTTF and the commonwealth were more concerned with performing a symbolic act than with giving the poor the essentials of a good life. Indeed, although the OTTF explicitly endorsed the equitable distribution of transplantation as an available means of "prevent[ing] the gulf between the haves and have nots from widening,"[73] the primary beneficiaries of the transplant policies adopted were not the less-well-off populations, from which a few transplant candidates might come, but those who could take public credit for making the humanitarian choice. The OTTF members, the public officials involved, and the citizens of Massachusetts as a whole avoided appearing cold-hearted and uncaring in the face of imminent death by symbolically extending

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71. On cost figures, see Massachusetts Task Force (1984: 43–69). These figures have been criticized as excessive (e.g., Overcast and Evans 1985: 107).

72. A better reading of the President's Commission report surely would conclude that the state ought to ensure equitable access to lower-cost, higher-priority services, leaving expensive technologies outside the "decent minimum" but available for purchase by those who choose to devote personal resources to that end.

73. The OTTF surely places disproportionate emphasis on catastropic health care as a way to rectify perceived injustices in the social order. It is open to challenge not only by those who would be prevented from purchasing transplants, but also by the have-nots in question, who might reasonably choose to have the resources applied where they have greater need and can expect greater benefit. It appears, however, that the OTTF had a larger political agenda. Chairman Annas has acknowledged as much in responding to criticisms such as those suggested here: "The Task Force . . . saw its charge as an opportunity to express our views on how the system *ought* to work. The Task Force belived that fairness and equity are critical values that are more important than perpetuating a system where only the rich and those with the right insurance or publicity acumen can obtain transplants. The fact that we have not tried for equity and fairness elsewhere in the system does not make it somehow wrong to take the opportunity we have in heart and liver transplantation to try to introduce equity and fairness in the real world. We must begin somewhere. Anywhere will entail some arbitrariness. But the symbolic nature of transplantation, and its ability to capture the public's attention and support, commend it as a reasonable place to begin. Far from presuming 'the validity of the status quo,' the Task Force believed that transplantation provides a unique opportunity to modify some of the health care system's fundamental operating assumptions" (Annas 1985d: 112–113). Annas's visionary goal is, however, as remote as ever. The OTTF report's passionate concern for equity ironically succeeds only in raising to the level of principle the political preference for identified over statistical lives, while doing little to clarify the debate over the extent to which government should guarantee the provision of health care services.

lifesaving assistance to a handful of afflicted patients. The troubling question remains, however, whether the commonwealth has so far discharged its other, perhaps greater responsibilities to its disadvantaged citizens that those basking in the glow of this good work are truly entitled to feel good about themselves.

The alternative of off-stage choices. Whenever tragic choices are made upon a public stage, it is probably inevitable that the actors will play to the audience, sacrificing some values, particularly allocative efficiency, in order to be seen as acting vigorously in the defense of human life. Before one can criticize the performance in Massachusetts, therefore, it is necessary to ask whether there is any way in which these difficult issues could have been resolved without public posturing and with a greater expectation that resources would not be used in pursuit of health benefits too modest to justify the outlays. Can the role of politics in these difficult matters be limited? One discussion of this question frames the challenge as follows:

> Although there are good reasons for our society to seek to spare its individual members catastrophic health care costs, in doing so it will almost inevitably commit more resources than it really wants to commit, or should commit, to such a purpose. This result is probable because government will find it difficult to impose, or even tolerate, needed limits on very expensive medical efforts to save lives and preserve health without seeming to deny the sanctity of human life. The challenge is thus to design social institutions which neither unduly sacrifice society's humanitarian ideals nor overspend on medical services not warranted by the benefits they yield. . . . Government cannot safely assume too central a role in decisionmaking on life-and-death and similar issues and . . . society will be better off if institutional arrangements are such that death and suffering from catastrophic disease continue to be perceived as "more an act of God than of the legislature." Careful attention to program details and to the allocation of decisionmaking responsibility is necessary if society is to succeed, in the context of expanded protection against catastrophic medical expenses, in preserving both humanitarian values and democratic government's benign—if not its beneficent—image (Havighurst, Blumstein and Bovbjerg 1976: 123–24).

The quoted study "identifies a critical need to keep government's profile low in order to facilitate saying 'no' when it is appropriate to do so" and "seeks to help government limit its moral as well as its financial exposure while honoring a substantial commitment to assist victims of catastrophic disease" (ibid.: 124).

The Massachusetts performance reviewed here casts only a little light on the possibility that government can be removed from center stage in these dramas and that there can be introduced instead the *deus ex machina* of an unregulated, demand-driven market for health services. The foundation of the Massachusetts sys-

tem is, after all, the assumption that regulation is essential to prevent inefficient growth and wasteful spending on health services of all kinds. Although there was a time when this assumption seemed unchallengeable, actual reforms in some health care financing mechanisms have recently begun to reveal the potential of private purchasing decisions in a comprehensive marketplace to curb the excessive flow of resources into the health care sector and to confine spending to activities that are relatively cost-effective (Arnett 1985: 1; Davis 1985: 81).

Certainly what is known about the efficacy and costs of liver transplantation does not suggest that only irrational or impoverished persons would ever choose to forgo this treatment even in the face of certain death.[74] It thus may be socially desirable and practically feasible to leave decisions about whether or to what extent to cover liver transplantation to private choices of employers, health insurers, and organized health plans, all of which are accountable to consumers in a competitive market.[75] Even where public financing is necessary, government may recede from its current role as dominant decisionmaker by cashing out current in-kind benefits and letting beneficiaries shop for private coverage with financial help in the form of a government-supplied voucher.[76] In this fashion, government can fulfill its responsibility for providing a decent minimum level of health services without having to rule definitively on what services beneficiaries must select.

Whether the performance of a competitive, demand-sensitive market for health care will satisfy the full range of public expectations is still an open question, but there is at least some evidence that health care consumers and providers are now economizing in ways previously resisted. Thus, it may be possible

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74. Available data suggest not only that liver transplantation is uniquely expensive but that it can plausibly be viewed as of questionable benefit. Although the OTTF report's survey of liver transplantation morbidity and mortality is brief (Massachusetts Task Force 1984: 29–32), other sources raise some important questions concerning the toxicity of cyclosporine, the effect of long-term administration of immunosuppressive drugs on the growth and development of children, and the near total lack of measures of the quality of survivors' lives (see NCHSR 1983; Starzl 1985). The OTTF addressed these major concerns only in connection with the prospect that too many transplant seekers might die in the state-mandated queue; if this happens, the OTTF report advocates that individuals meeting the medical criteria for inclusion "be persuaded not to attempt to join the queue" by telling them the truth about transplantation (Massachusetts Task Force 1984: 83). The implication is that if people understood all of the risks, consequences, and side effects of transplantation and their implications for the duration and quality of life of survivors, a significant number of candidates would voluntarily forgo the procedure. One would suppose that potential candidates deserve the opportunity to achieve that full understanding regardless of the size of the organ supply. The OTTF was even further, of course, from seeing any connection between doubts about the value of the procedure and the procedure's extraordinary costs; it was also opposed to letting individuals compare likely benefits and costs before deciding whether to invest in the necessary insurance (ibid.). The Minnesota Coalition (1984: 47–48) report specifically contemplates such choices.

75. Allowing individual consumers to exercise free choice creates problems of adverse selection and may be questionable policy for other reasons. See note 77.

76. The Minnesota coalition (1984: 38–41) discusses two alternative strategies for "implementing the 'basic level of health care' principle." One of these is a voucher-type strategy that would leave the private sector substantial decisionmaking freedom.

> . . . to eschew trying to solve the [catastrophic disease] problem in any definitive fashion and instead to take steps to enhance each individual's ability to solve his own personal problem by choosing among a variety of available options, with public financial assistance where necessary. Such a strategy lacks the tidiness and specificity which policymakers often desire and would doubtless leave many residual problems. . . . But the fundamental values of pluralism and freedom . . . suggest an obligation not only to tolerate but also to foster diversity on matters as intensely personal and private as the means of coping with life-threatening disease and the attendant tragic choices (Havighurst, Blumstein and Bovbjerg 1976: 189).

Such an approach provides a major challenge to society's ability to educate consumers and foster rational decisionmaking about low-probability events.[77]

The Massachusetts experience with liver transplantation yielded one interesting datum helpful in appraising the market alternative when MBCBS offered TIP at an actuarially fair price to their group accounts and fewer than one-third of them accepted the offer. Unanswered, of course, are many questions, including the ultimate one—whether a situation in which some citizens are protected against a highly visible health care need and others are not is a stable and tenable one or one that would disintegrate upon the appearance of a transplant candidate who turned down the available protection. This empirical question deserves more thoughtful attention than it has yet received. For example, it would not be conclusive evidence against relying upon market choices to ration transplantation if an occasional patient should receive, at an employer's or insurer's expense, a treatment that was not included in purchased coverage. Informal provision of such charity for occasional exceptionally appealing cases is not an unthinkable alter-

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77. The simple view is that "organ transplantation is the epitome of an insurable event; transplants are random, rare, their risk probabilities are measurable, and transplants are prohibitively expensive for most individuals" (Minnesota Coalition 1984: vi). But letting *individuals* choose is not necessarily the optimal policy. For example, Calabresi (1974: 48, 52) observes, "I'd like to know, for instance, if any individual does value his own life in a way that can meaningfully be used in choosing between life and death risks. If each of us were paid to take a one in a million chance to lose our life, realistically, how much would we ask? How much more would we ask if the chance of death were one in one thousand? Or one in two? I would suggest that the value that most of us would give to our lives would not be the same value in the three cases, after discounting by mathematical risk. In other words, the value we as individuals put on our life is not independent of the gamble we are taking. This fact makes it very, very difficult as a practical matter to define any value as the appropriate one in creating incentives for safety." For findings from psychological research suggesting inconsistencies and incoherence in consumer decisions that require the weighing of risks and valuation of alternative outcomes, see Kahneman and Tversky (1982) and Tversky and Kahnemann (1981). Although these difficulties suggest the shortcomings of individual choice, most market choices of insurance coverage are not made by uninstructed consumers. Instead, they are most likely to emerge from collective processes in employment groups and to reflect the sophistication of employers, insurers, and medical care providers. Such collective choices are likely alone to reflect both shared values and the existence of alternative uses of the resources at stake.

native to the Massachusetts rationing system. Indeed, it could supply just the buffer against highly publicized denials of care that is needed to maintain an effective barrier to spending vast resources on marginally beneficial treatments.

Attention must also be given to the design of coverage that can survive the inevitable questioning and legal challenges. One can imagine, for example, insurance policies that provide liver transplants for the most appealing patients, such as children, but deny them to victims of less attractive diseases, such as alcoholism. Other mechanisms for controlling costs and ensuring quality include limiting coverage to transplants obtained in centers that have been identified by the insurer as efficient and low-cost. Although much remains to be learned about whether and how to purchase this costly and still questionable service, privatization of catastrophic insurance, perhaps with tax and other incentives to encourage coverage broad enough to minimize the demoralizing effects of tragic choices, would seem to make possible sensible rationing techniques that the public sector could not itself sustain.[78]

Perhaps the best way to conclude this reflection on how society handles these difficult matters is to ask how these problems will be addressed a hundred years from now. Is there any doubt that society will somehow reassess its commitment to saving lives without regard to cost and will come to accept as a matter of course some deaths that could be prevented by the application of high technology? There are many different ways in which patients can be selected for treatment, not all of which require reliance on government to act directly or indirectly as the giver or denier of life itself. Without question, our attitudes toward such matters are changing. Ultimately, we must give up some cherished but so far unexamined collective beliefs. The frightening but certain truth is that we are acting out our own morality play—one in which simplistic values, of the kind that flourish most in a political environment, must eventually give way to some hard realities of the human condition. As in any great drama, the central question is whether other, more vital values will be preserved.

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